Functional Outcomes After Spinal Cord Injury

PARADIGM®

OUTCOMES

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Speaker Bio

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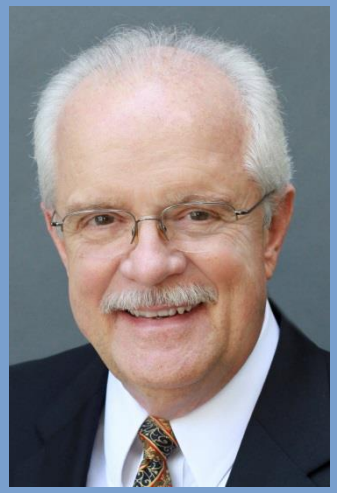


- Paradigm Medical Director
- 30 years of experience in caring for patients with spinal cord injuries
- Board certified in physical medicine and rehabilitation
- Served for 10 years as the chairman of the steering committee for the Consortium for Spinal Cord Medicine
- Past-president of the American Spinal Injury Association

Objectives

- Anticipate functional outcomes after traumatic spinal cord injury (SCI) and the trajectory of motor recovery for complete and incomplete injuries by:
  - **Level of injury**
  - **ASIA/ISNCSCI Impairment Scale**
  - **Time course of motor recovery in "key muscles"**
  - **Affect of comorbid conditions**
  - **Ambulation options**

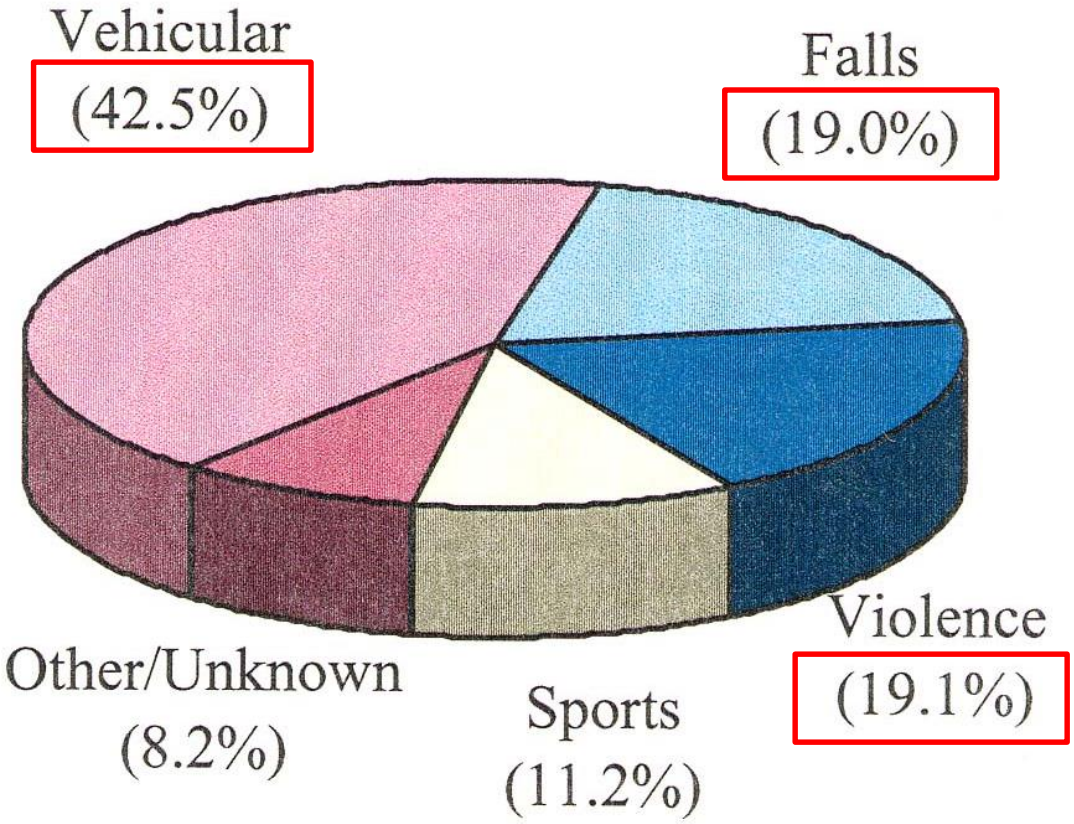
Agenda

- Acute SCI diagnosis & evaluation
  - Common syndromes
  - Motor recovery time course
- Outcomes by level of motor complete injury
- Impact of secondary and co-morbid conditions
- Ambulation outcomes
  - Historical ambulatory aides
  - Exoskeleton criteria
  - Exoskeleton options

Etiology of SCI

Annual incidence 25-35/million general population

Grouped Etiology



Factors That Affect The Transverse and Longitudinal Extent of Injury

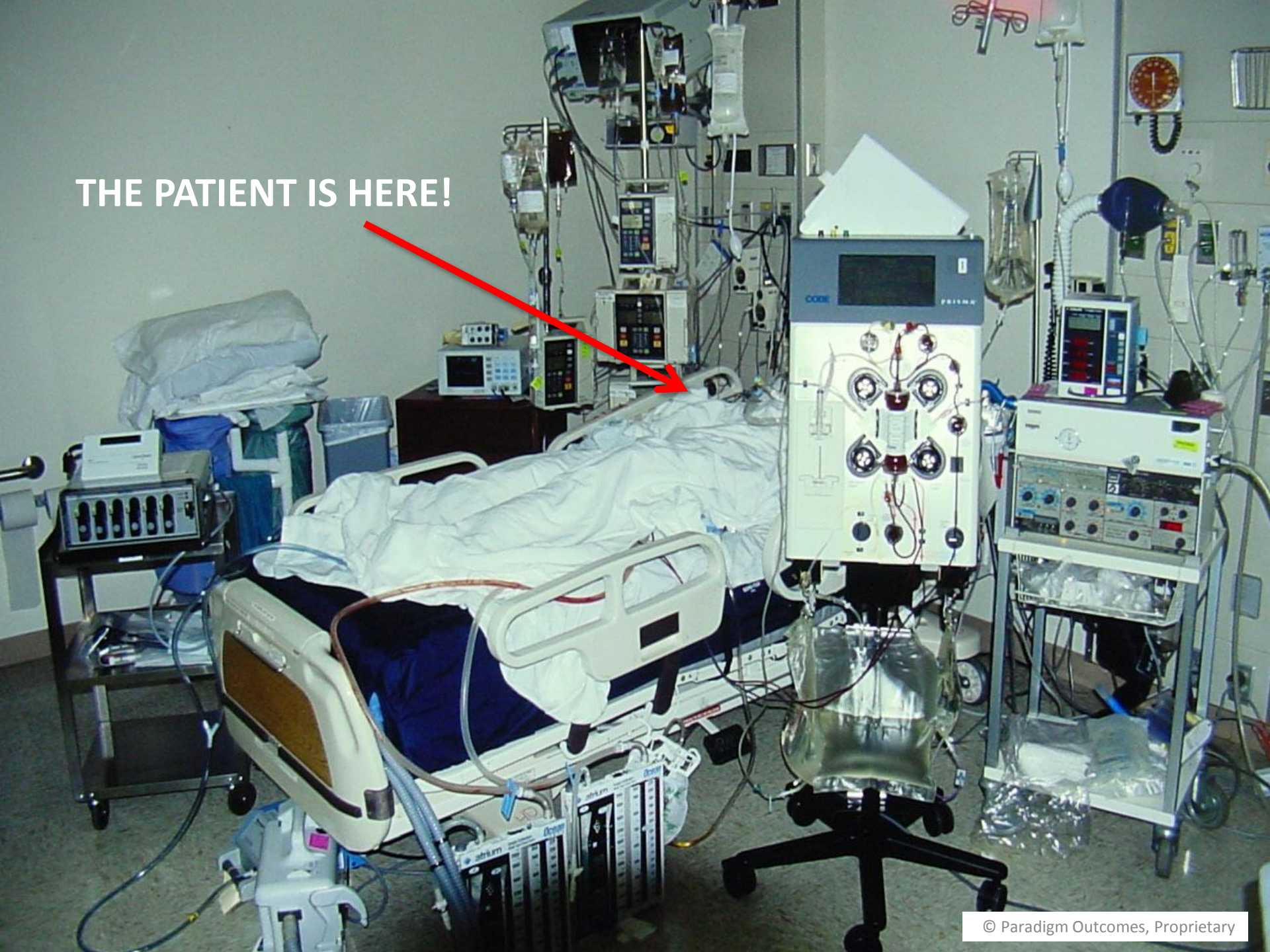
- Severity of impact trauma & spine distortion
- Secondary trauma
  - Brain injury
- Cardiopulmonary complications:
  - Hypotension
  - Hypoxia

SCI Emergency Procedures at Scene

The goal of emergency management is to preserve axons in the spinal cord and prevent complications:

- Immobilize spine
- Support lordosis
- Logroll when turning
  - Pressure relief
  - Bronchial drainage
- Remove from hard surface ASAP

Initial Evaluation



CT: Computerized Tomography

- Bone detail
- Reformatting images
- After metrizamide myelography

Figure 1. *Fracture-dislocation of cervical spine with dural tear. Axial postmyelography CT image through the C5-6 disc. Fractures of the vertebral body (solid curved arrows) and widening of the facet joint space (straight arrows) can be seen. Leakage of myelographic contrast into the right C5-6 facet joint space and leakage into the posterior paraspinal soft tissues indicate a dural tear (open curved arrows).*

MRI: Magnetic Resonance Image

- Visualize soft tissues
  - Spinal canal and cord dimensions
  - Occult disc herniation
- Cord edema vs. hemorrhage

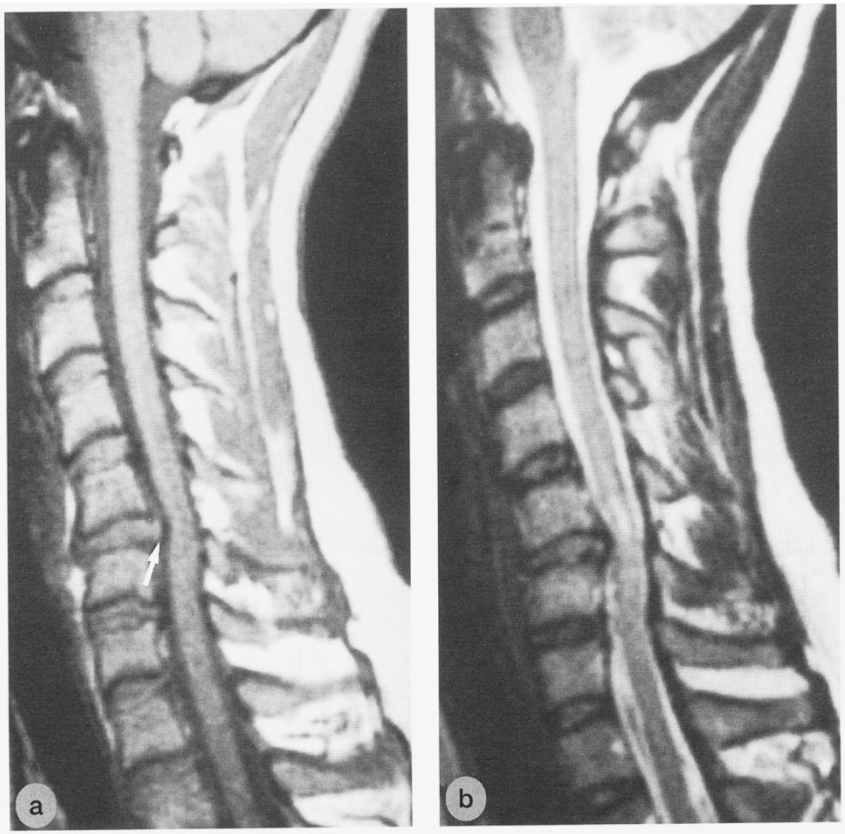
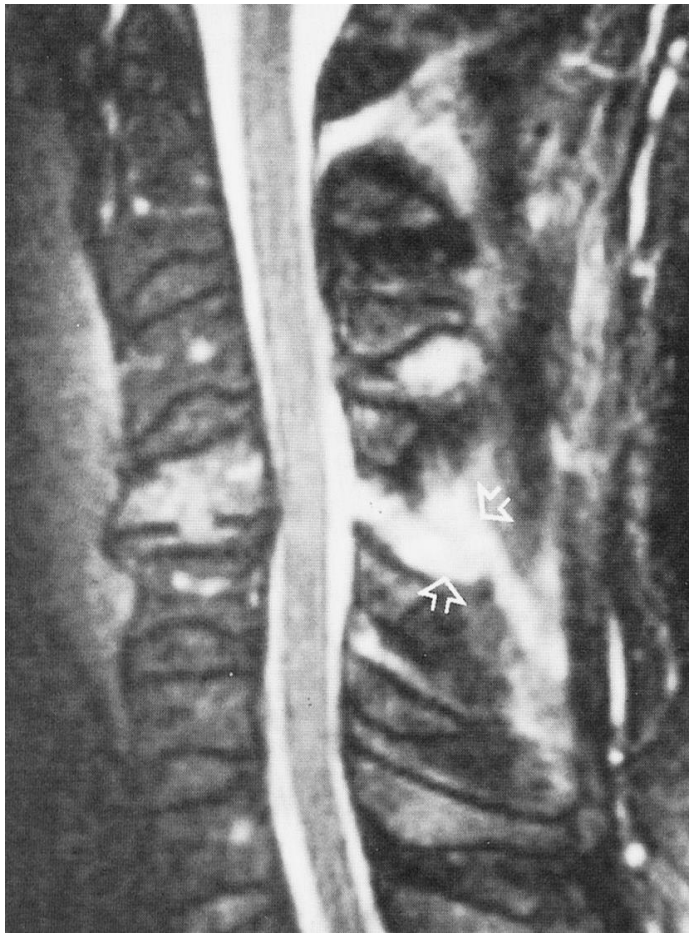


Figure 4. *Traumatic cervical disc herniation. Sagittal short TR/short TE (T1-weighted)* ***(a)*** *and sagittal long TR/long TE (T2-weighted)* ***(b)*** *spin-echo MR images of the cervical spine. T1- and T2-weighted images demonstrate posterior extrusion of disc material causing compression of the cervical spinal cord (arrow). The T2-weighted sequence also demonstrates increased signal within the cervical cord indicating cervical cord contusion. There is effacement of the CSF space both anterior and posterior to the cord.*

MRI Evaluation

- Disruption of inter-spinous ligament
- Compression fracture of C4
- Discontinuity of inferior end plate



Evaluation of Complex Injuries

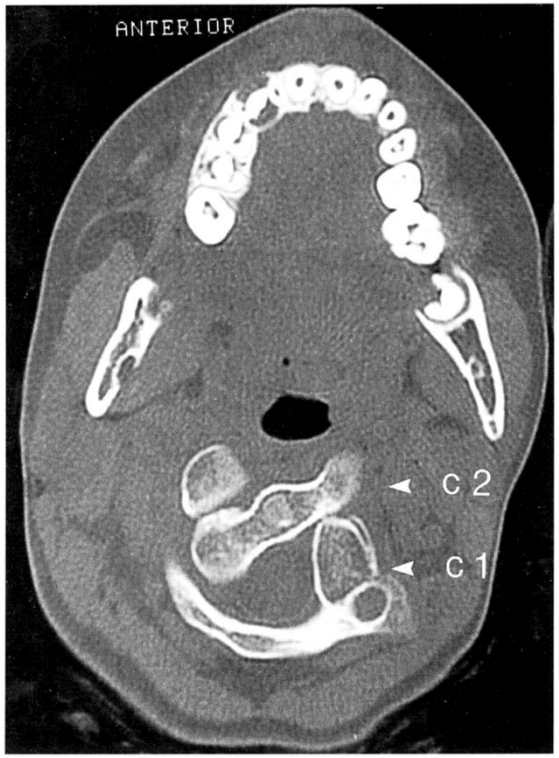


Figure 1. *Computed tomography scan through C1 and C2 illustrating a case of atlantoaxial rotatory dislocation. Valuable information is gained regarding bony alignment and the likely position of the vertebral arteries.*

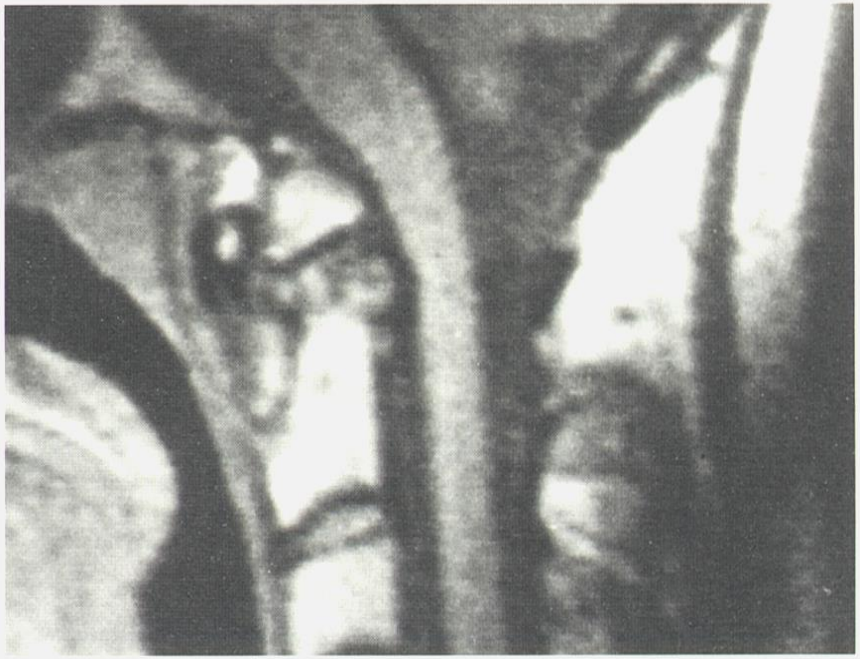
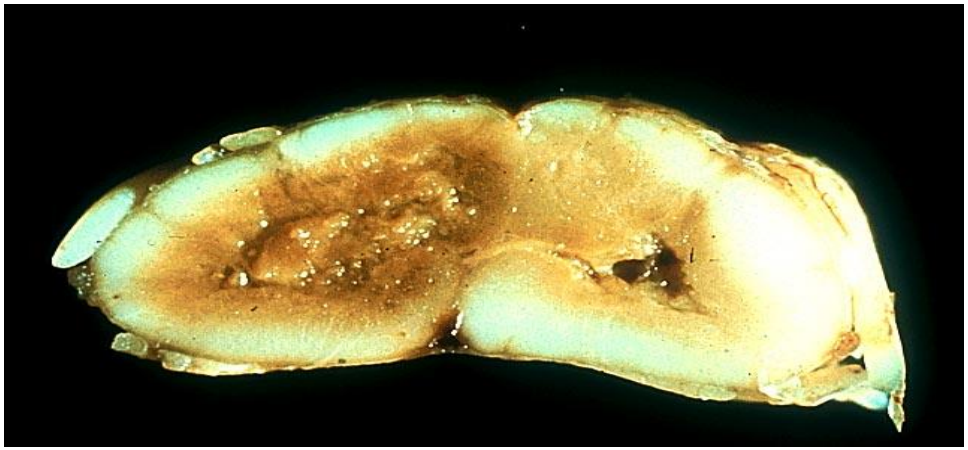
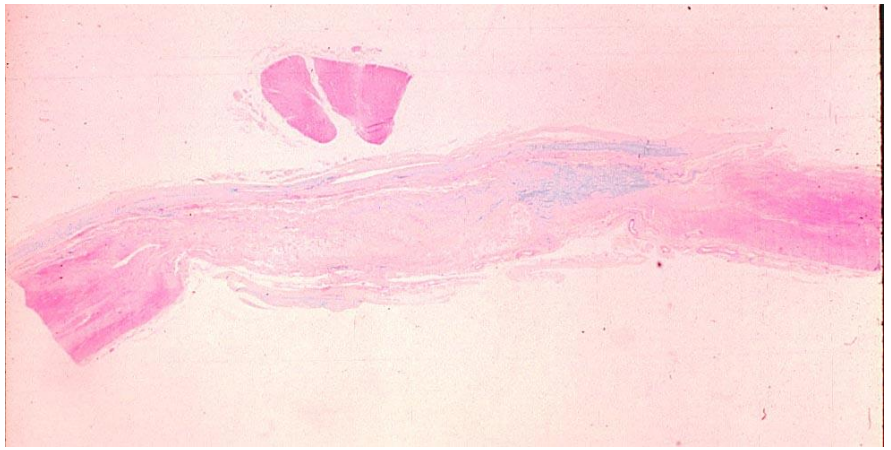


Figure 2. *Magnetic resonance image, sagittal plane, demonstrating a type II odontoid fracture with interposition of the transverse ligament between the odontoid process and the body of C2.*

Evaluation of Complex Injuries





Evaluation of Complex Injuries

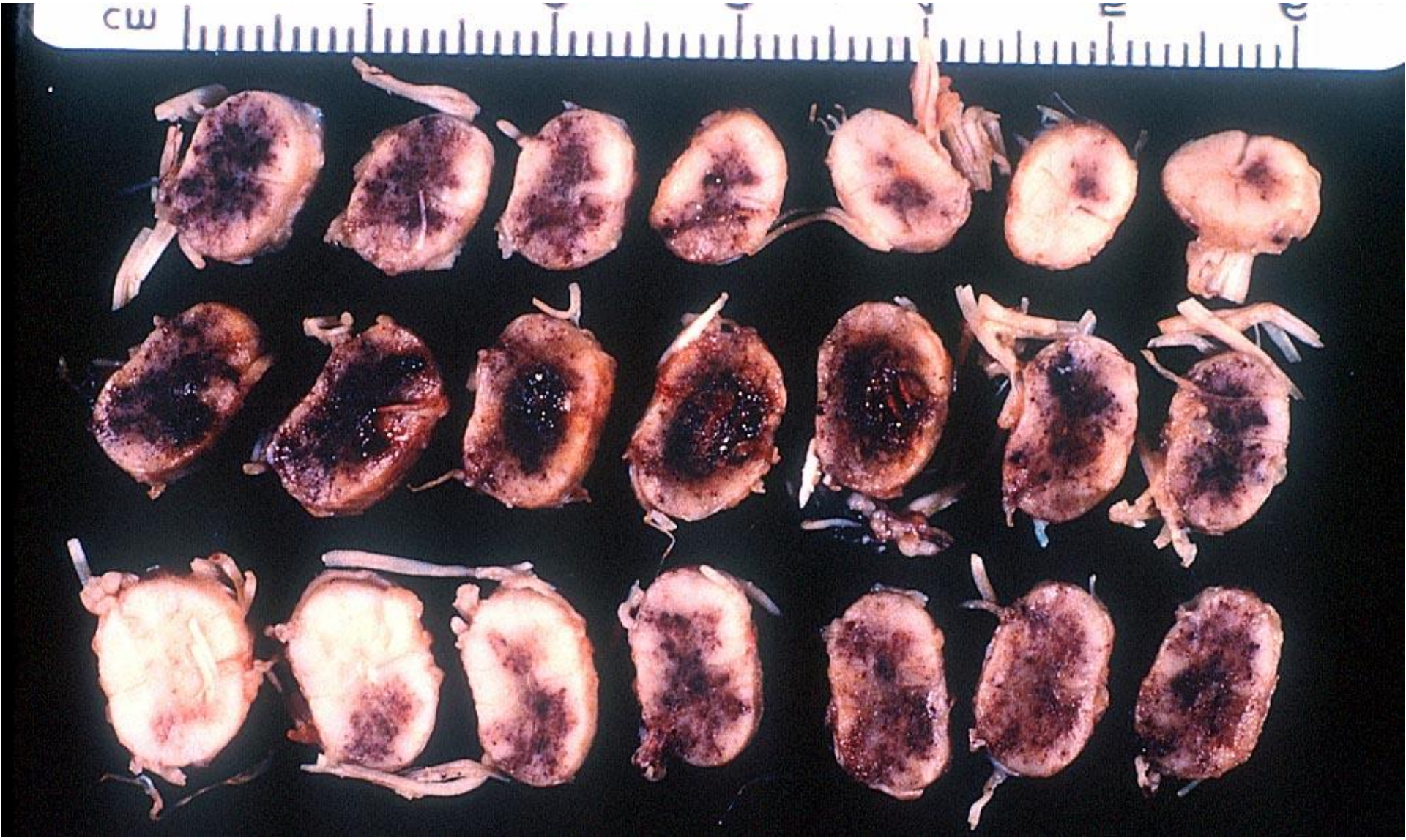
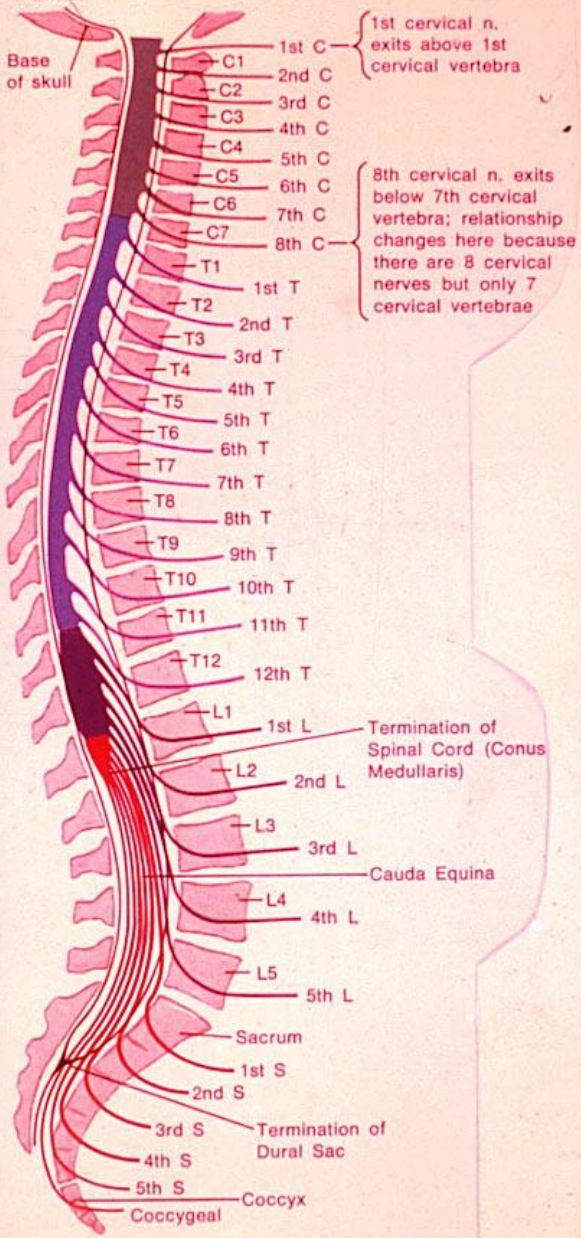
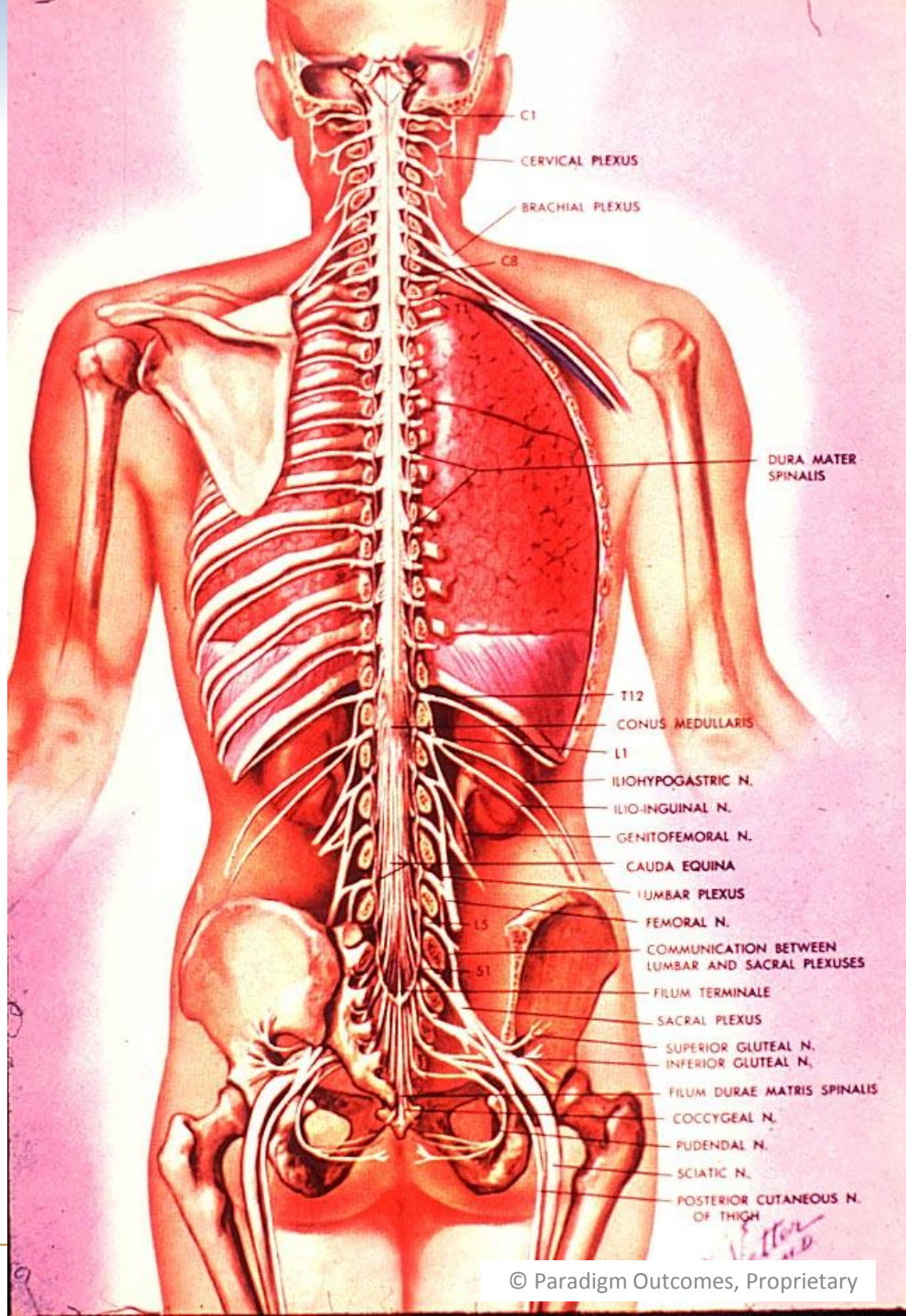


PLATE 2

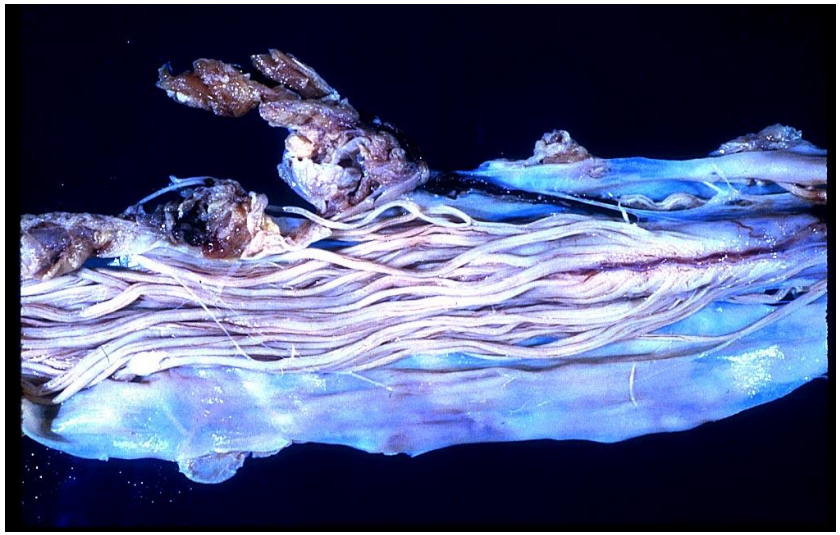


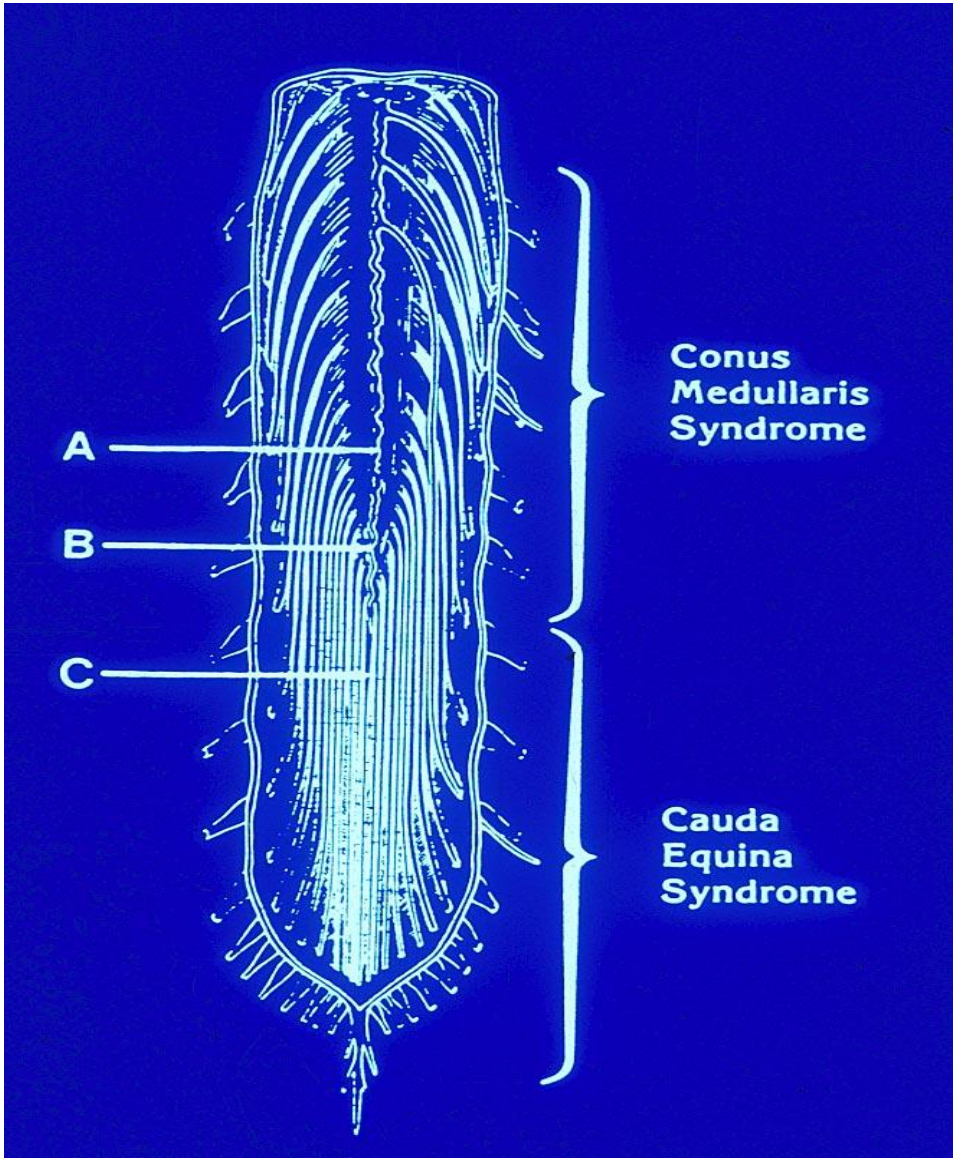
Relation of spinal nerve roots to vertebrae: vertebrae numbered in cardinal numbers, nerve roots in ordinal numbers

Cervical
Thoracic
Lumbar
Sacral and coccygeal

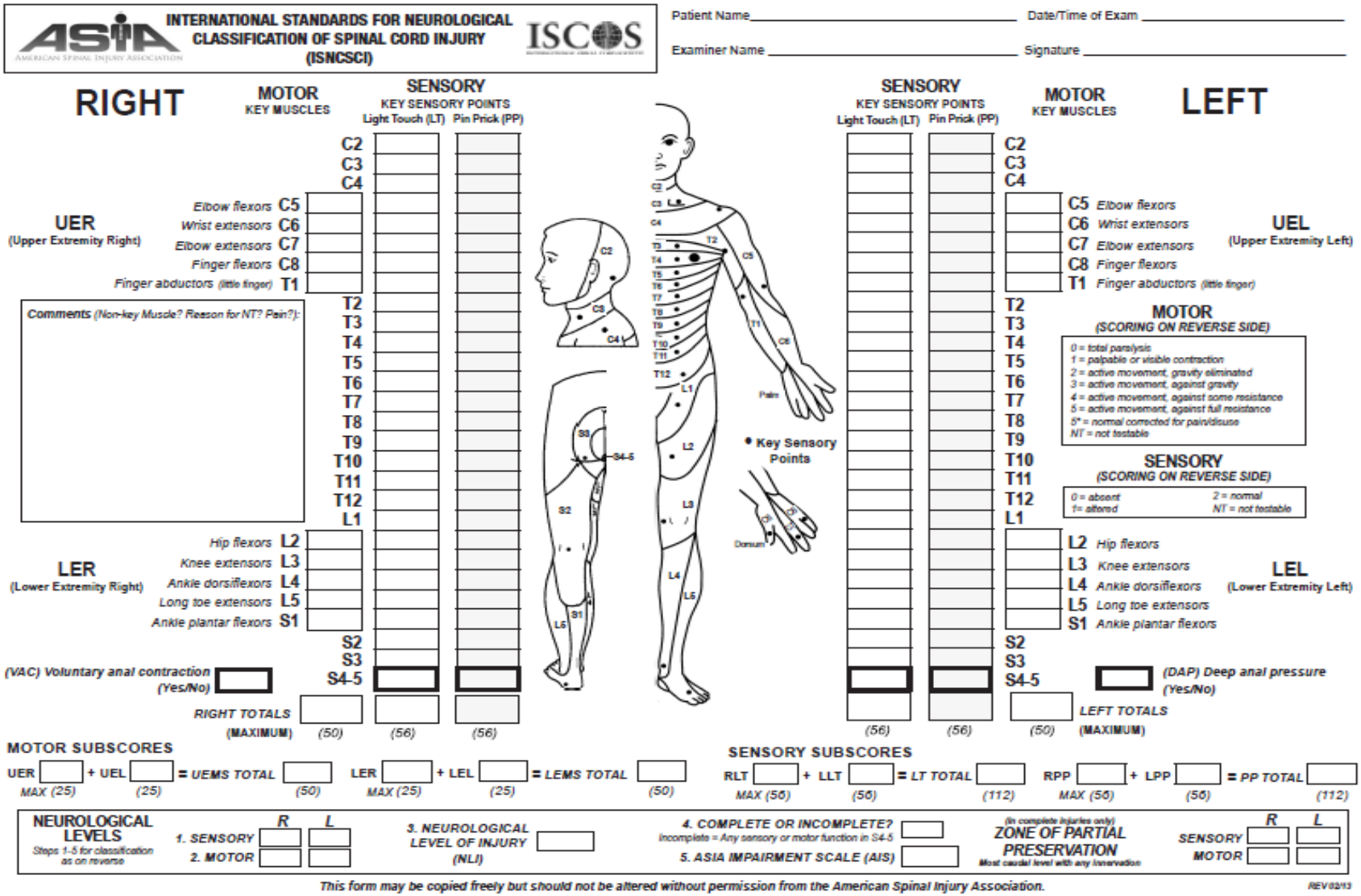


Conus vs. Cauda Equina Injury?

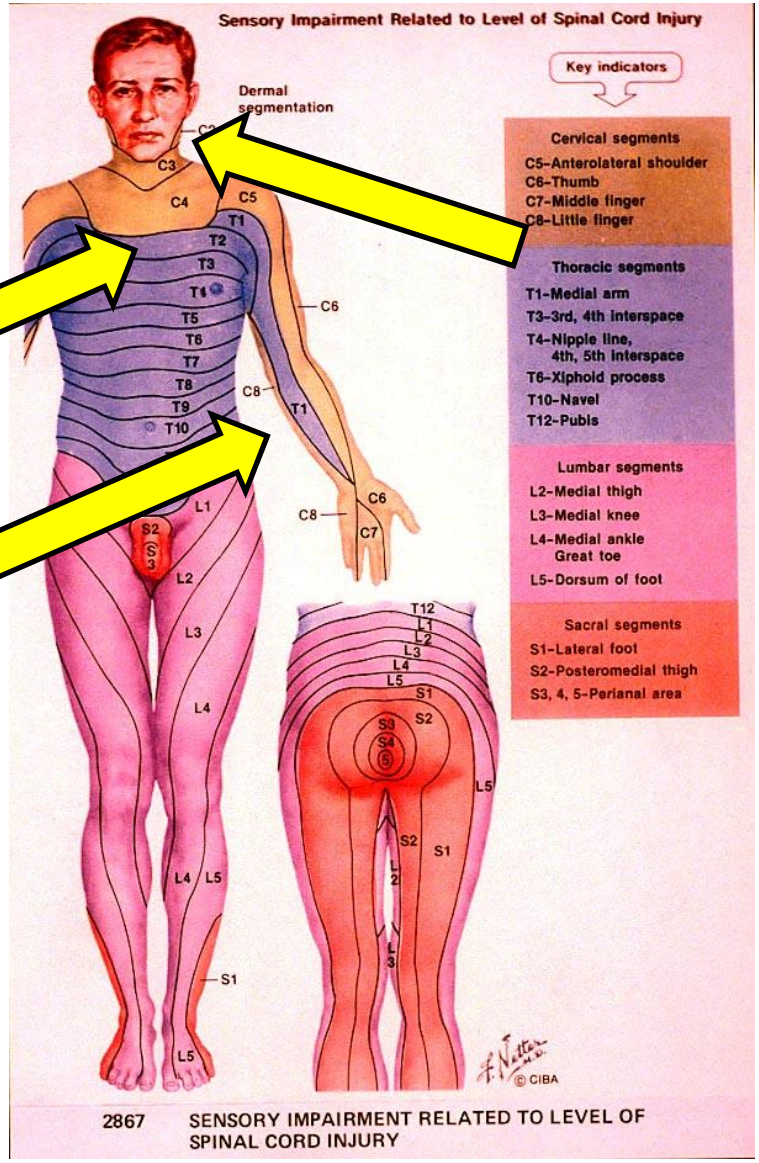


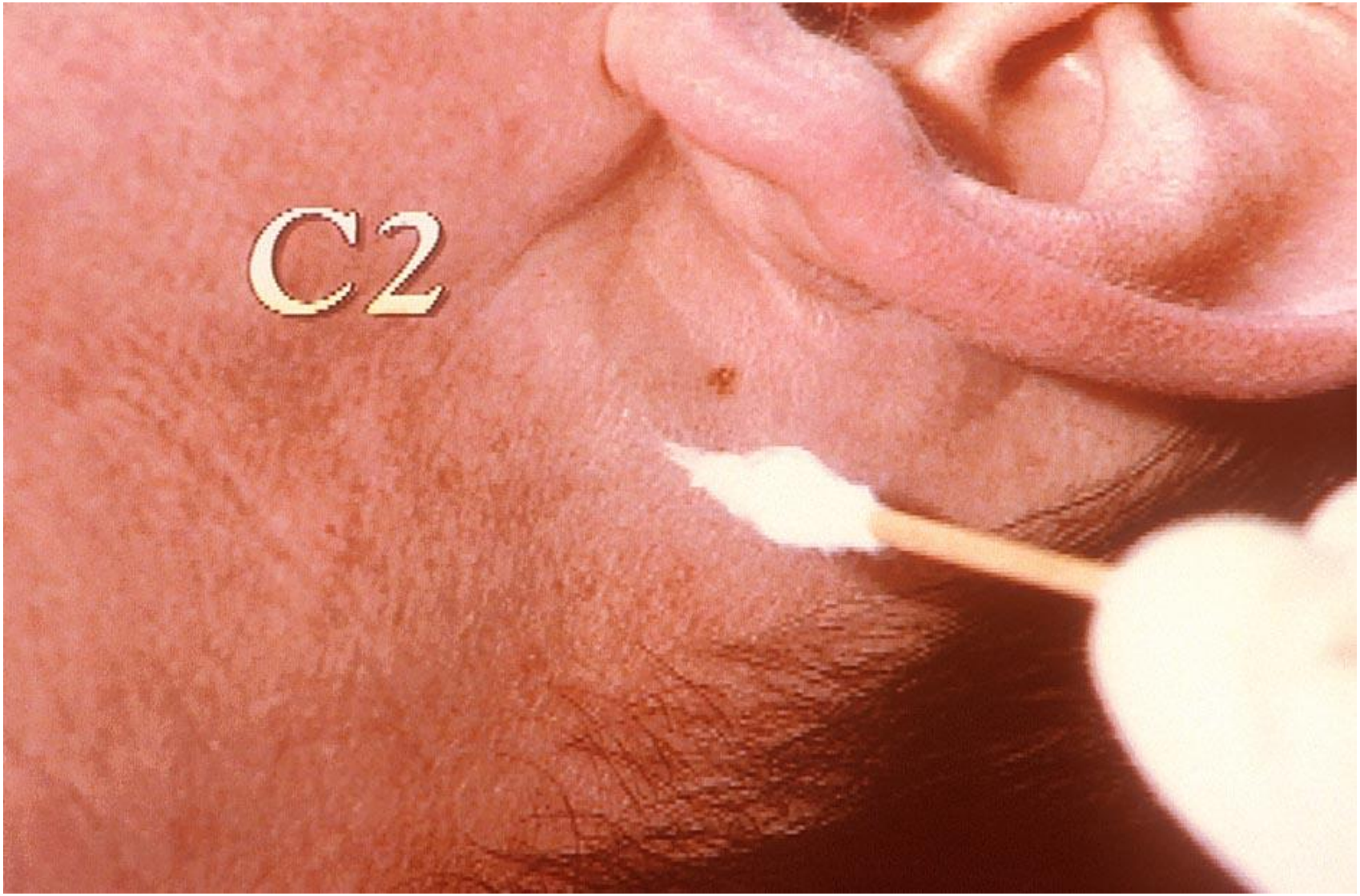


ASIA/ISNCSCI Impairment Scale



Common Errors in Sensory Maps & Testing





Sensory Evaluation on the Face

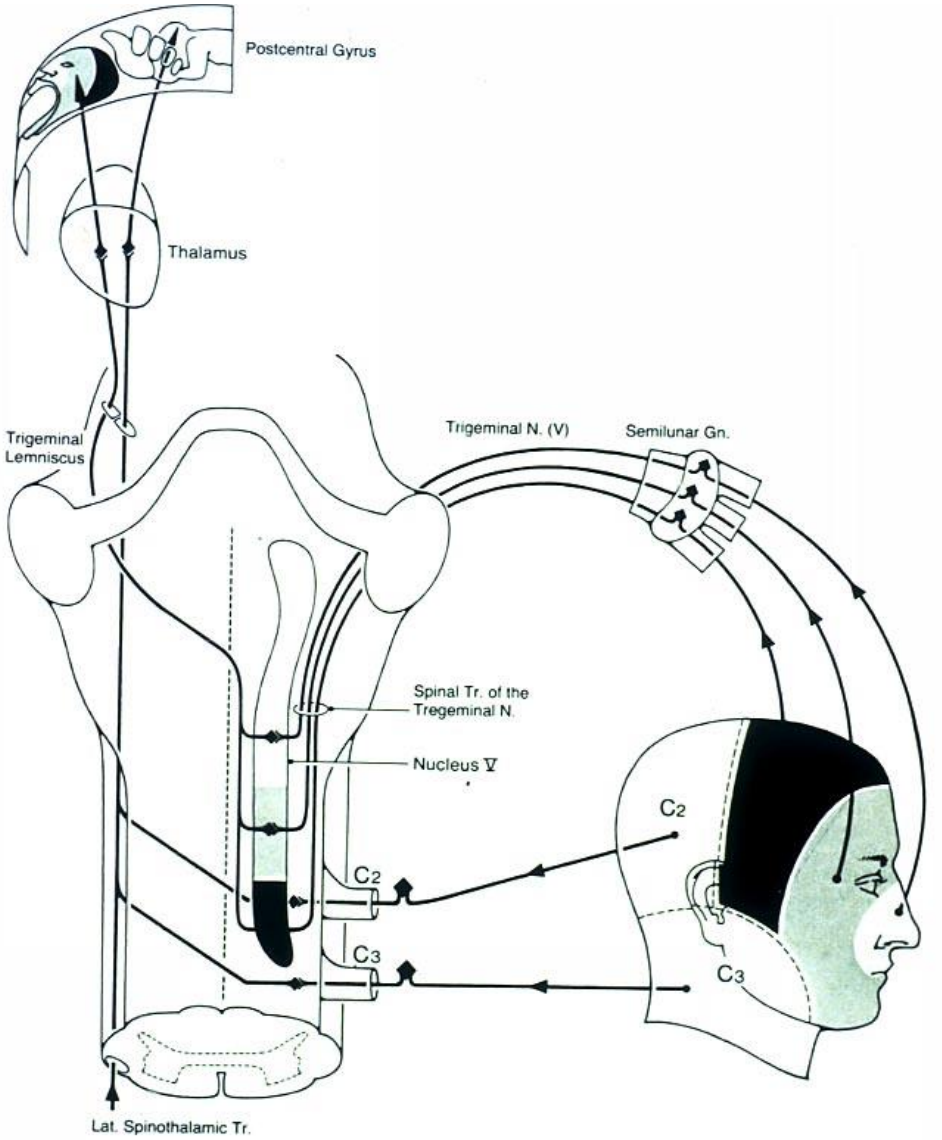


Fig. 54 Anatomic basis of (dissociated) sensory disturbances in the face.

Sensory Pathways

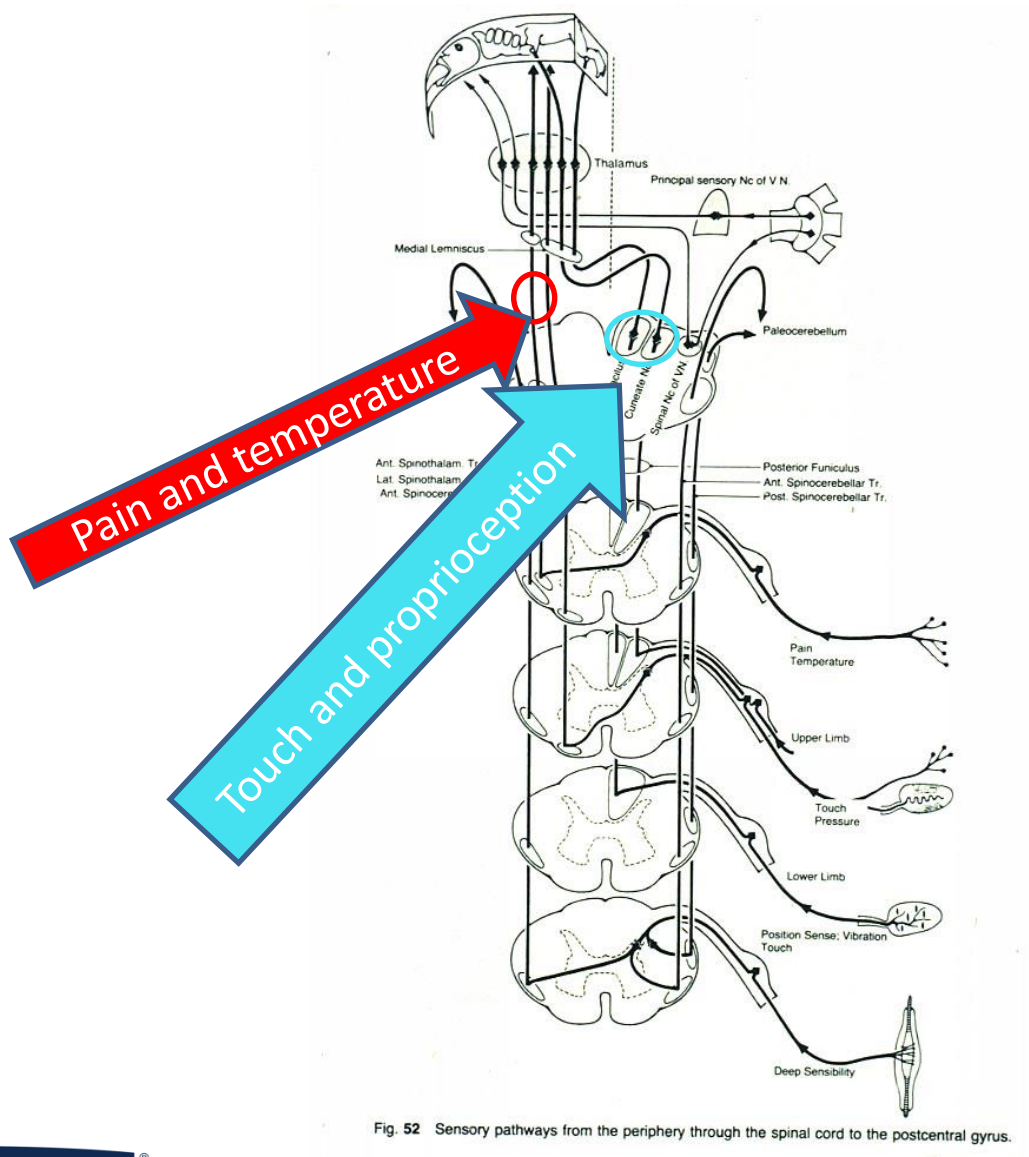
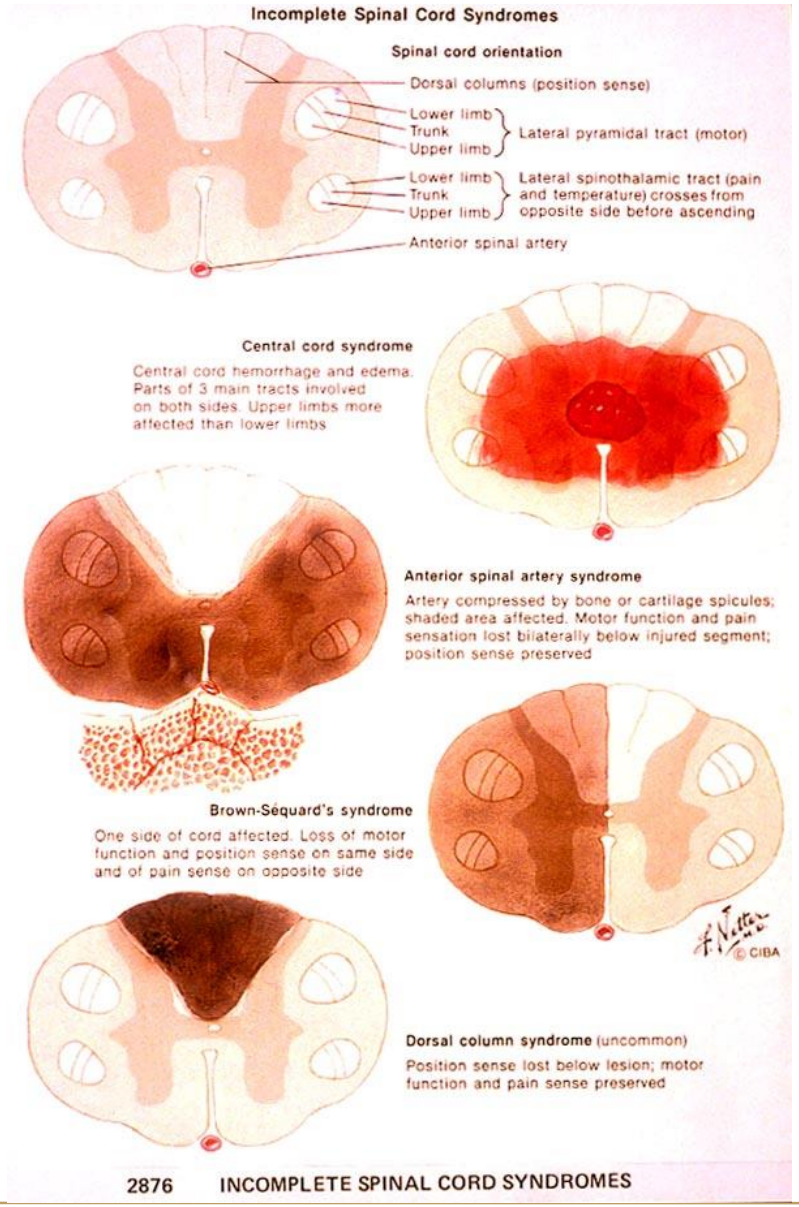


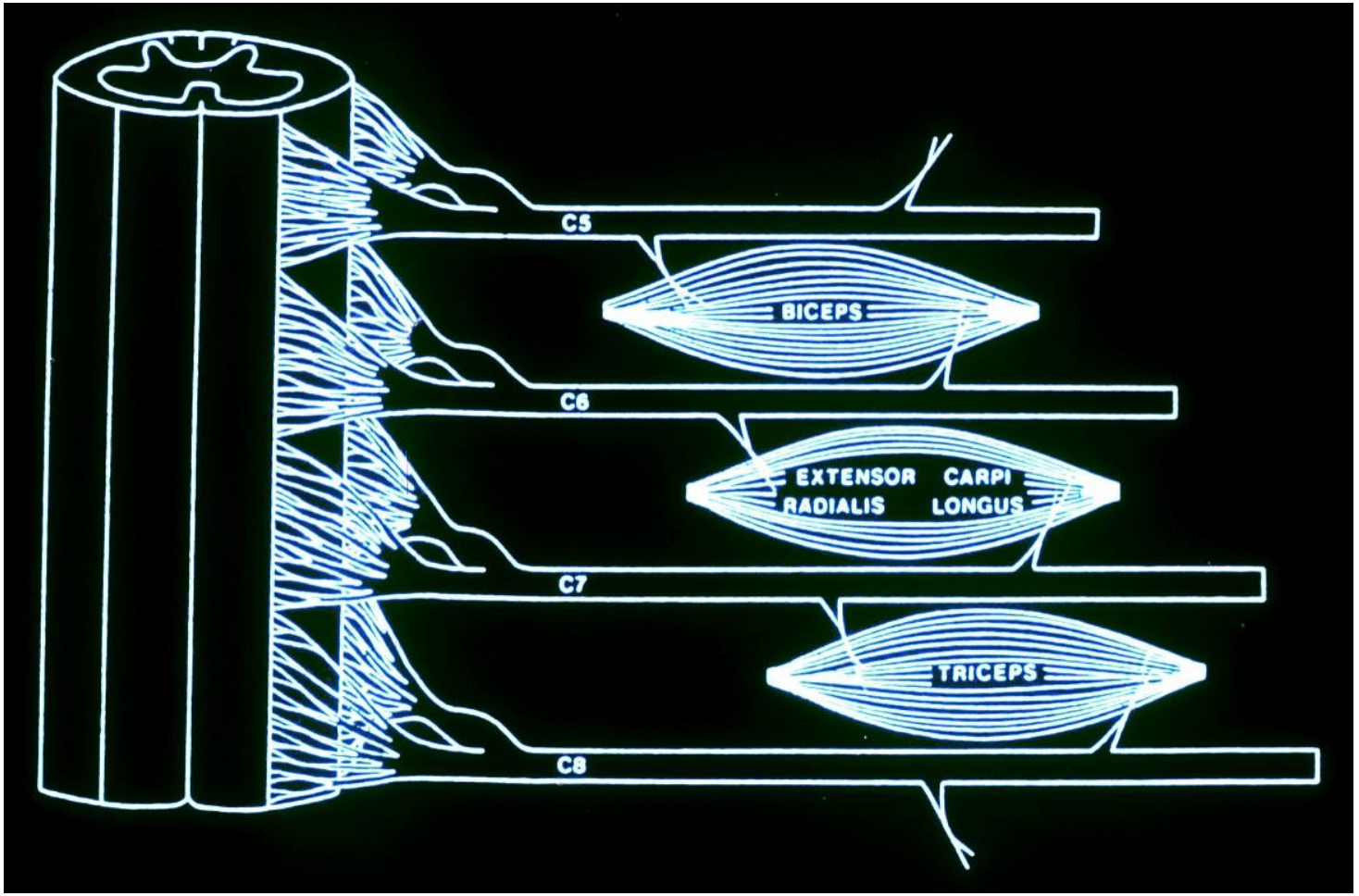
Fig. 52 Sensory pathways from the periphery through the spinal cord to the postcentral gyrus.

Incomplete SCI Syndromes

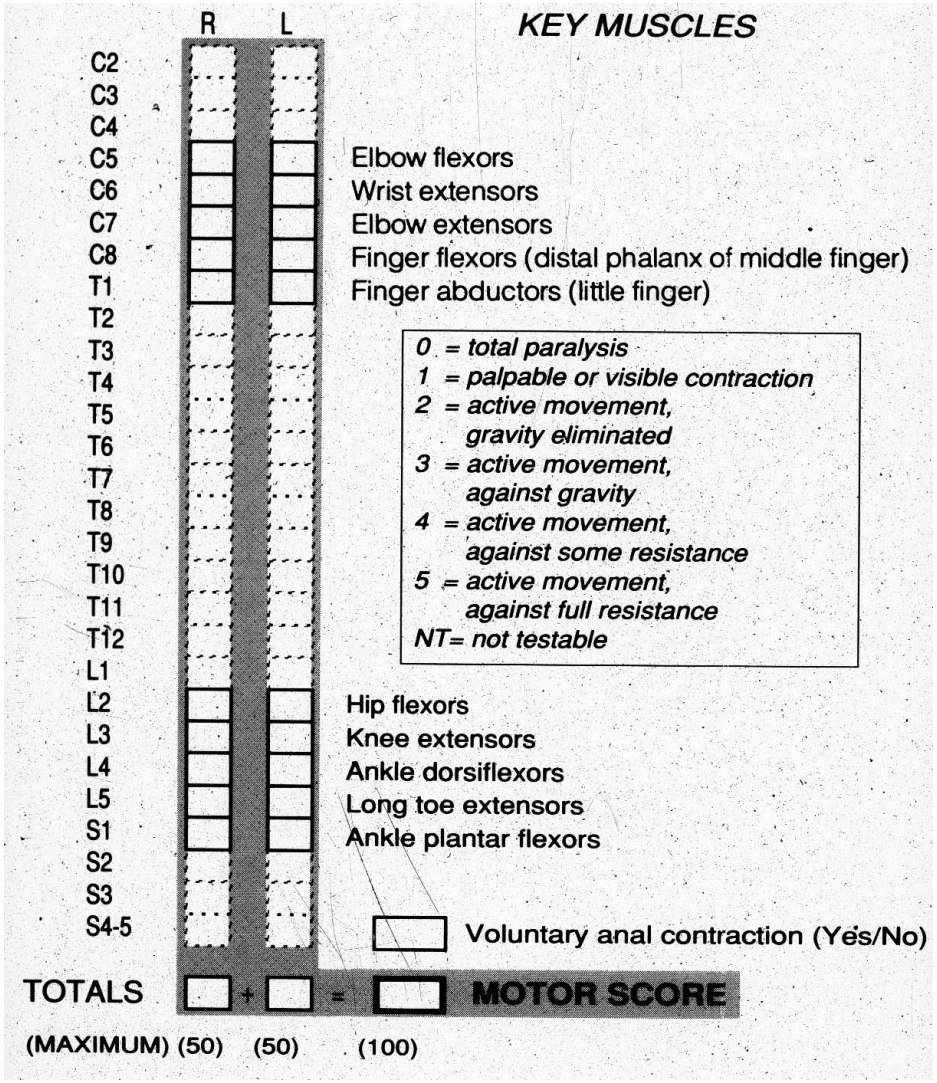


“Motor Sparing”

Motor level of injury



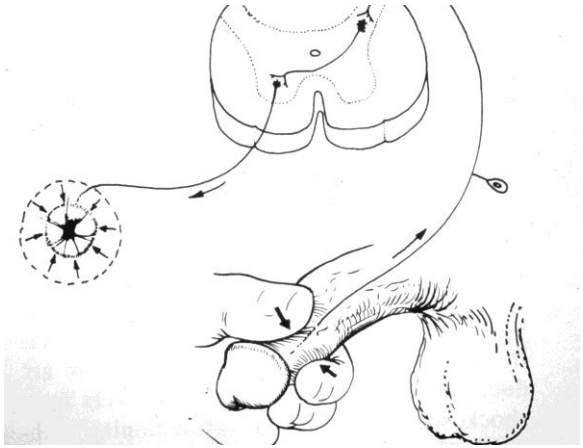
Motor Key Muscles



Sacral Sparing

Neurologic rectal exam

1. Peri-anal pin sensation
2. Proprioception
3. Voluntary sphincter contraction
4. Pelvic reflex



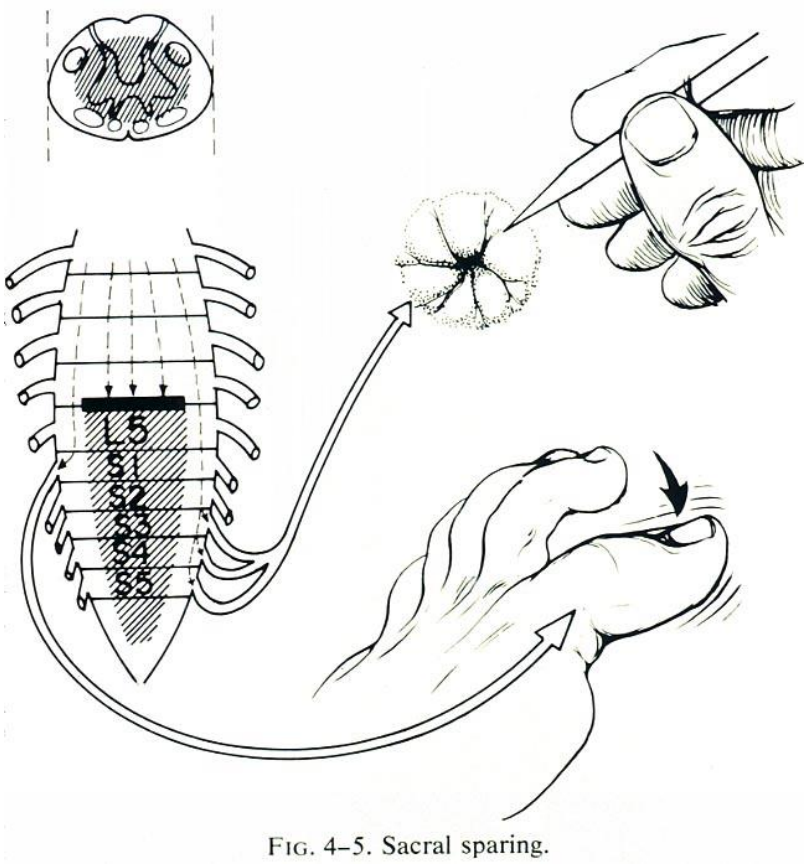
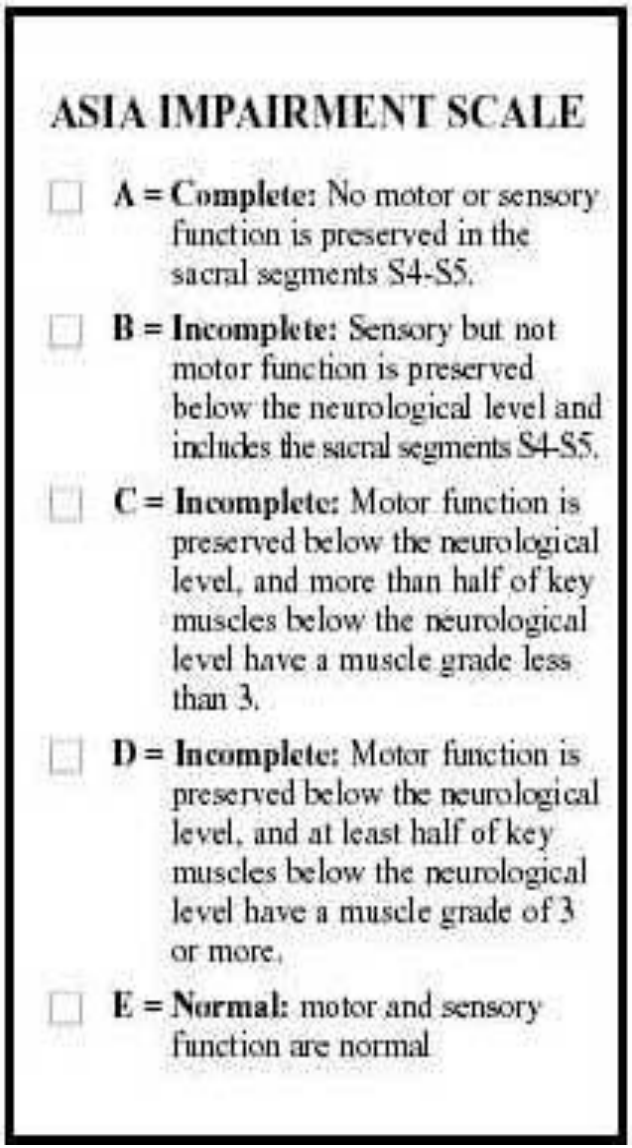


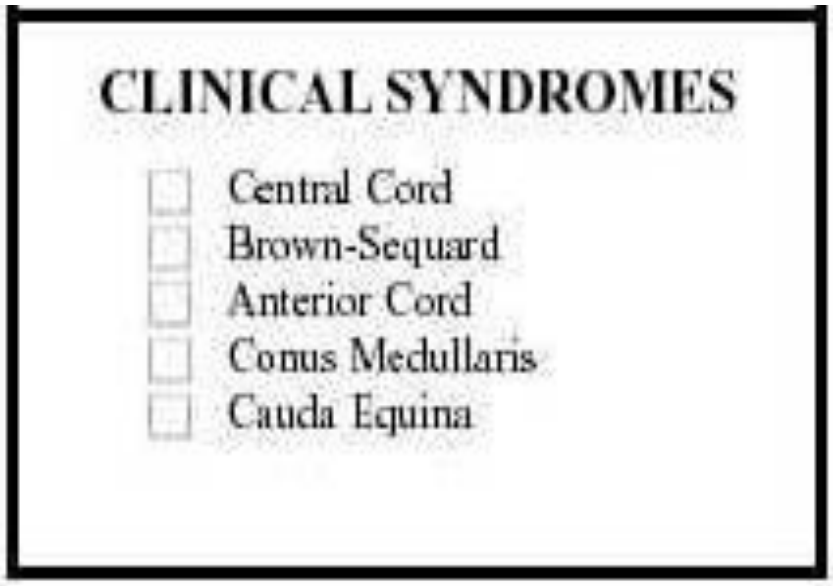
FIG. 4–5. Sacral sparing.

ASIA/ISNCSCI Impairment Scale



ASIA IMPAIRMENT SCALE

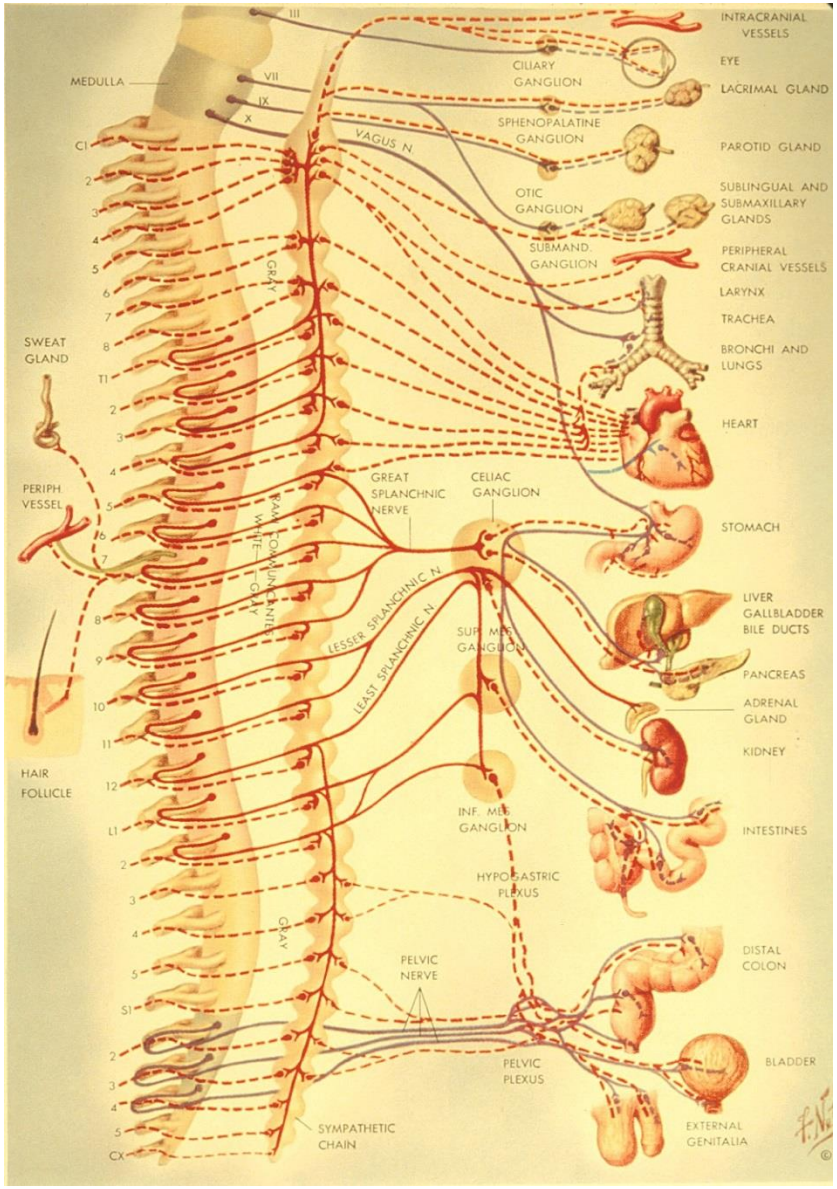
- ☐ **A = Complete:** No motor or sensory function is preserved in the sacral segments S4-S5.
- ☐ **B = Incomplete:** Sensory but not motor function is preserved below the neurological level and includes the sacral segments S4-S5.
- ☐ **C = Incomplete:** Motor function is preserved below the neurological level, and more than half of key muscles below the neurological level have a muscle grade less than 3.
- ☐ **D = Incomplete:** Motor function is preserved below the neurological level, and at least half of key muscles below the neurological level have a muscle grade of 3 or more.
- ☐ **E = Normal:** motor and sensory function are normal



CLINICAL SYNDROMES

- ☐ Central Cord
- ☐ Brown-Sequard
- ☐ Anterior Cord
- ☐ Conus Medullaris
- ☐ Cauda Equina

Impairment of the Autonomic Nervous System After SCI



Functional Outcomes By Level of "Motor Complete" Injury

C1-3

C4

C5

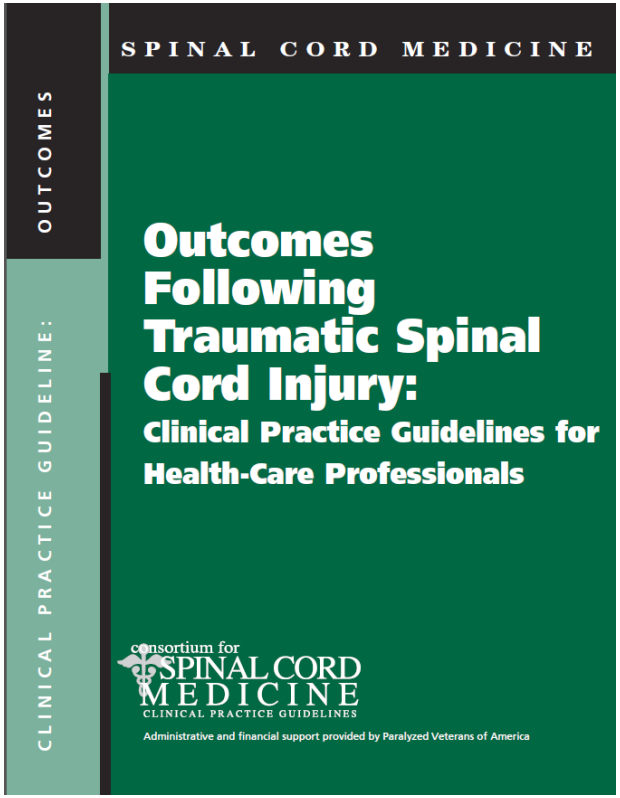
C6

C7-8

T1-9

T10-L1

L2-S5



http://www.pva.org/site/apps/ka/ec/product.asp?c=ajIRK9NJLcJ2E&b=6423003&en=atJJKXMDI9LSJ7NGI8LPL3PQLnJUI3NIJhIVJeNYLxE&ProductID=883869

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PARADIGM OUTCOMES

C7-8 Motor Complete Outcomes

TABLE 6. Expected Functional Outcomes **Level C7-8**

Functionally relevant muscles innervated: Latissimus dorsi; sternal pectoralis; triceps; pronator quadratus; extensor carpi ulnaris; flexor carpi radialis; flexor digitorum profundus and superficialis; extensor communis; pronator/flexor/extensor/abductor pollicis; lumbricals [partially innervated]
Movement possible: Elbow extension; ulnar/wrist extension; wrist flexion; finger flexions and extensions; thumb flexion/extension/abduction
Patterns of weakness: Paralysis of trunk and lower extremities; limited grasp release and dexterity secondary to partial intrinsic muscles of the hand

FIM/Assistance Data: Exp = Expected FIM Score / **Med** = NSCISC Median / **IR** = NSCISC Interquartile Range
NSCISC Sample Size: FIM=43 / Assist=35

	Expected Functional Outcomes	Equipment	FIM/Assistance Data Exp	Med	IR
Respiratory	Low endurance and vital capacity secondary to paralysis of intercostals; may require assist to clear secretions.				
Bowel	Some to total assist	• Padded tub bench with commode cutout or shower commode chair • Adaptive devices as needed	1–4	1	1–4
Bladder	Independent to some assist	Adaptive devices as indicated	2–6	3	1–6
Bed Mobility	Independent to some assist	Full electric hospital bed or full to king standard bed			
Bed/Wheelchair Transfers	Level: Independent. Uneven: Independent to some assist	With or without transfer board	3–7	4	2–6
Pressure Relief/ Positioning	Independent	• Wheelchair pressure relief cushion • Postural support devices as indicated • Pressure-relief mattress/or overlay may be indicated			
Eating	Independent	Adaptive devices as indicated	6–7	6	5–7
Dressing	Independent upper extremities; independent to some assist lower extremities	Adaptive devices as indicated	4–7	6	4–7
Grooming	Independent	Adaptive devices as indicated	6–7	6	4–7
Bathing	Upper body: Independent; Lower extremity: Some assist to independent	• Padded transfer tub bench or shower/commode chair • Handheld shower • Adaptive devices as needed	3–6	4	2–6
Wheelchair Propulsion	Manual: Independent all indoor surfaces and level outdoor terrain; some assist with uneven terrain	Manual: Rigid or folding lightweight or folding wheelchair with modified rims	6	6	6
Standing/ Ambulation	Standing: Independent to some assist Ambulation: Not indicated	Hydraulic or standard standing frame			
Communication	Independent	Adaptive devices as indicated			
Transportation	Independent car if independent with transfer and wheelchair loading/unloading; independent driving modified van from captain's seat	• Modified vehicle • Transfer board			
Homemaking	Independent light meal preparation and homemaking; some to total assist for complex meal prep and heavy housecleaning	Adaptive devices as indicated			
Assist Required	• Personal care: 6 hours/day • Homecare: 2 hours/day		8*	12*	2–24*

*Hours per day.

Expected Functional Outcome Categories

1. Respiratory function
2. Bowel function
3. Bladder function
4. Bed mobility
5. Bed/wheelchair transfers
6. Wheelchair propulsion
7. Pressure relief/positioning
8. Standing/ambulation
9. Eating
10. Grooming
11. Dressing
12. Bathing
13. Communication methods
14. Equipment required
15. Transportation options
16. Homemaking skills
17. Assistance required

FIM: Functional Independence Measure

Lower numbers mean greater burden of care

Thirteen motor items graded 1 to 7

7. Complete independence (timely, safely)
6. Modified independence (device, extra time)
5. Supervision

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4. Minimal assist (subject does 75%+)
3. Moderate assist (subject does 50-74%)
2. Maximal assist (subject does 25-49%)
1. Total assist (subject does 0-24%)

Medical Equipment Required

- Minimum recommendations
- DME and adaptive devices
- Guidelines are non-prescriptive recommendations
- Generic descriptions
- Individualized to each person after assessment
- Thorough testing required to demonstrate safety and effectiveness before purchase
- Disposable medical products are not included

Expected Respiratory Equipment

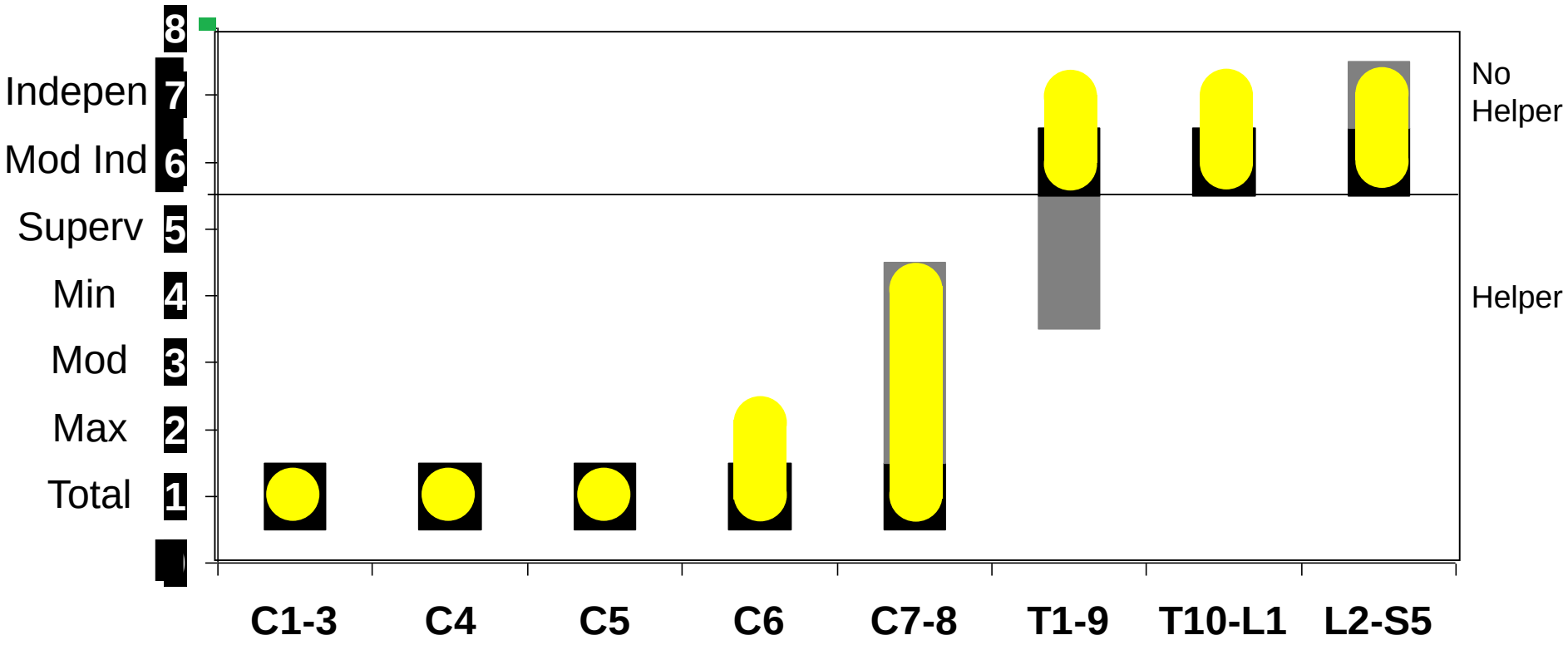
C1-3: Two ventilators (bedside, portable) plus ET suction equipment or other suction management device plus generator/battery backup

C4: Same as C1-3 if not ventilator free

C5-S5: No ventilator equipment required (unless…?)

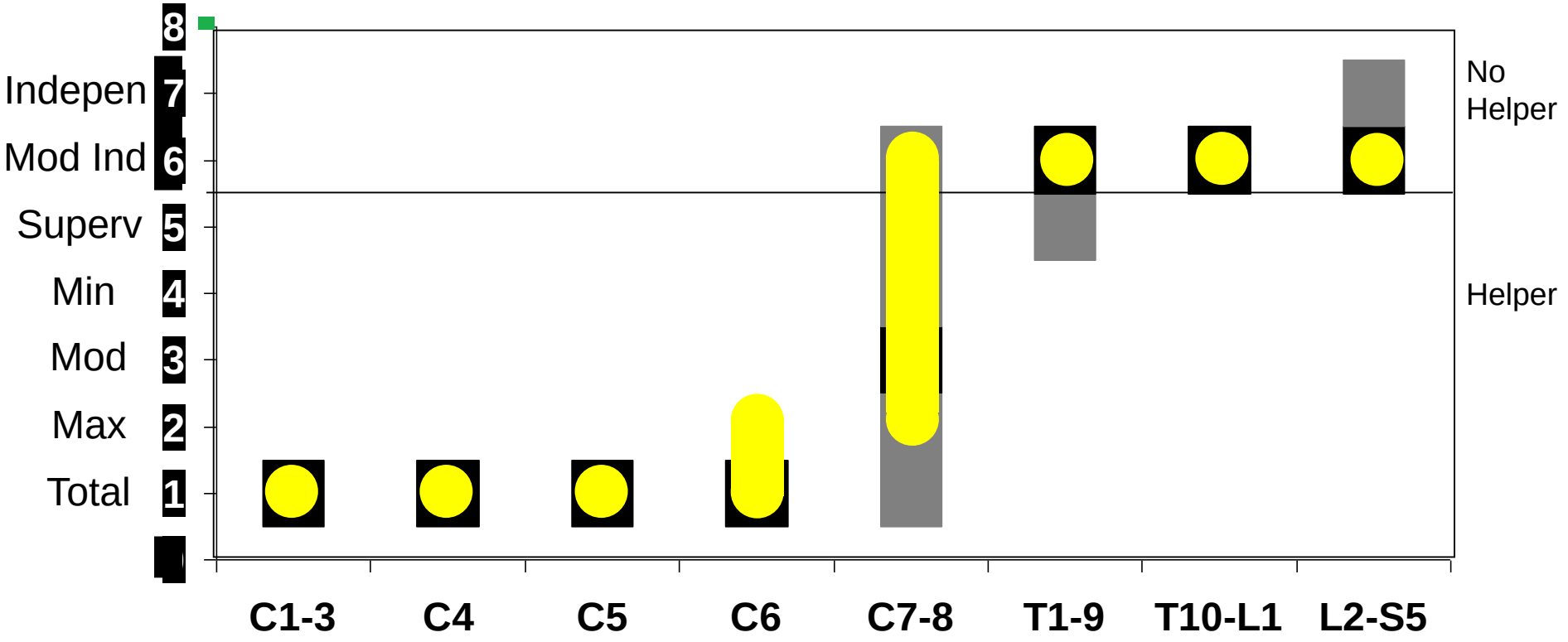
Expected FIM

Bowel Scores



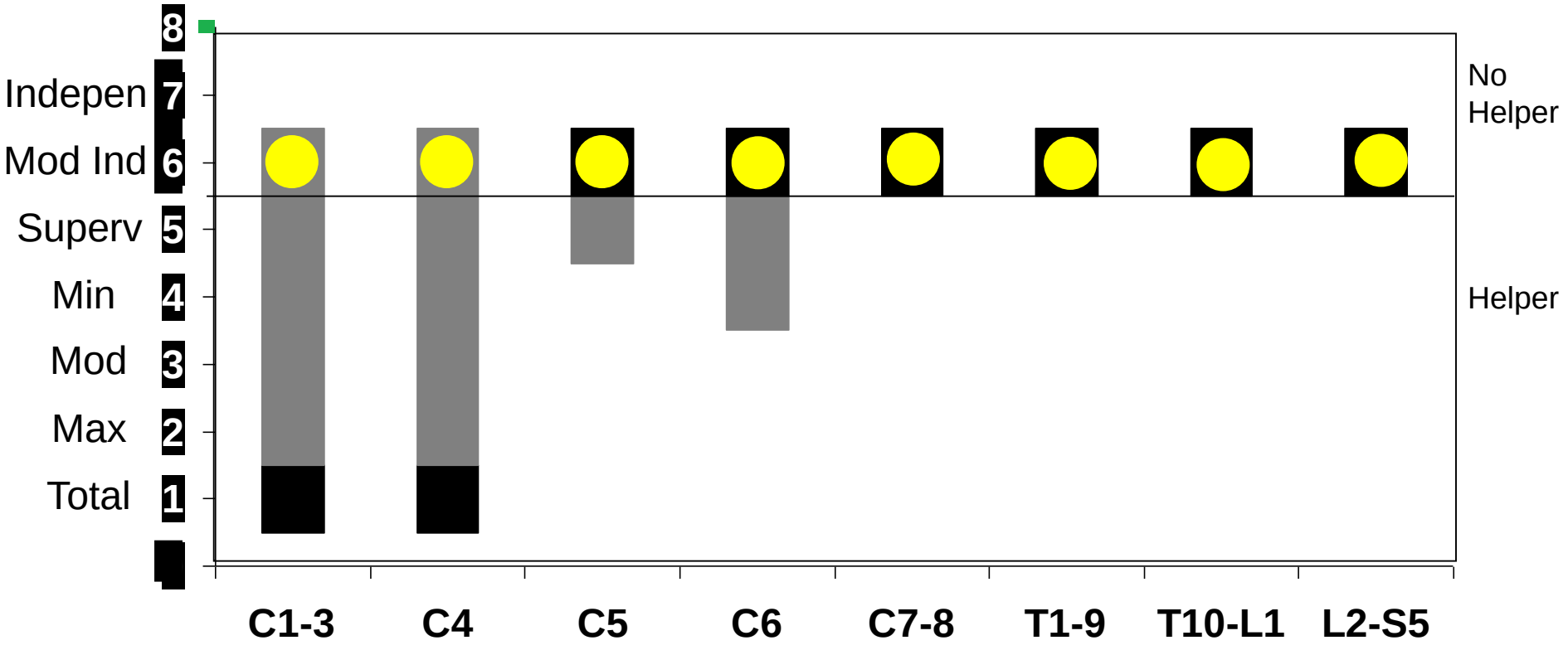
Expected FIM

Bladder Scores



Expected FIM

Wheelchair Propulsion Scores



Assistance Required From Outcomes CPG

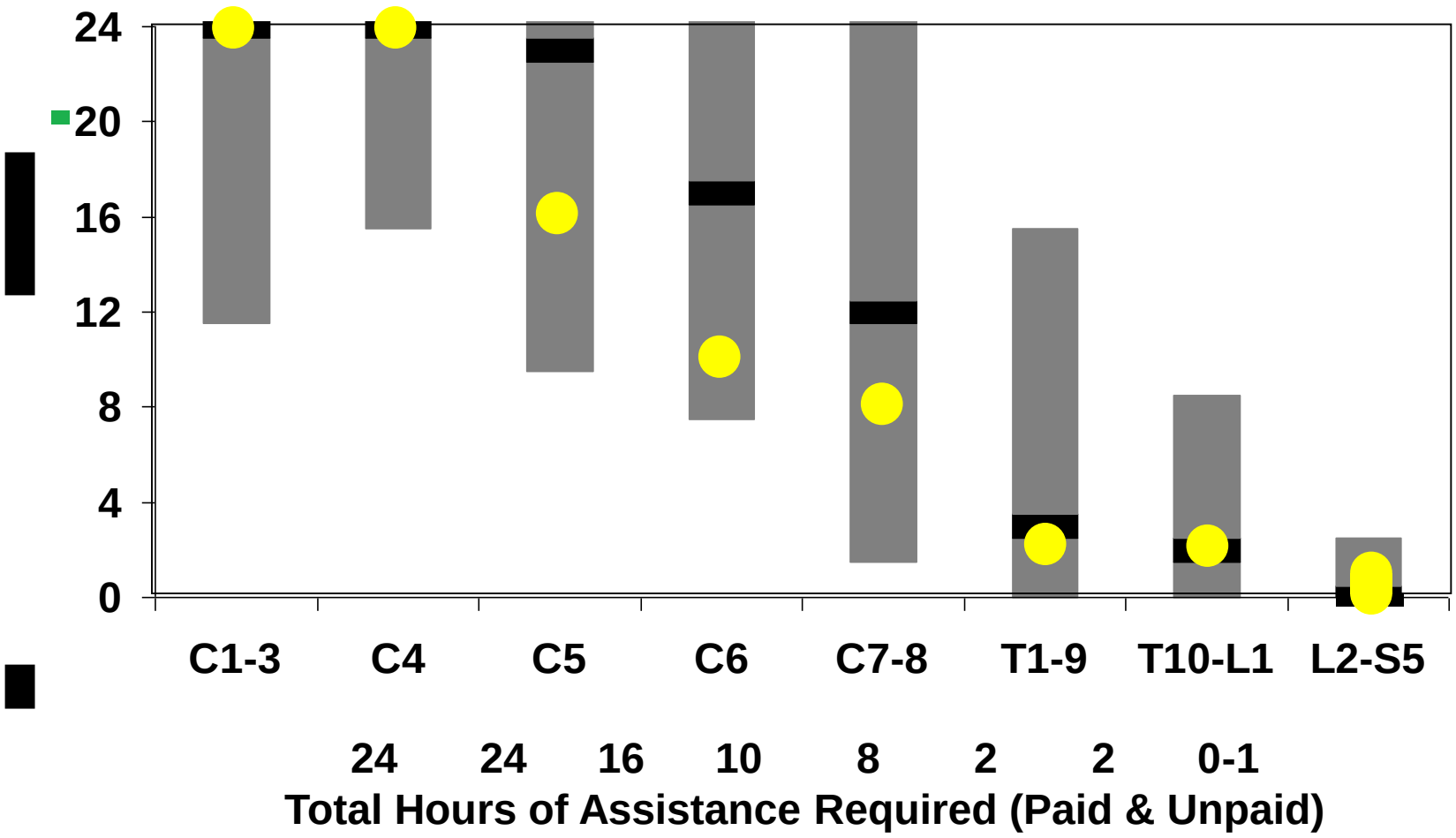
- Number of hours required from a caregiver to assist with personal care and homemaking activities in the home
- Safety and independence concerns
- Paid and unpaid hours
- Skilled and unskilled services combined
- Needs may change with aging, weight gain, etc.
- Wide range of individual variables

FIM Assistance Data Cited in Outcomes CPG

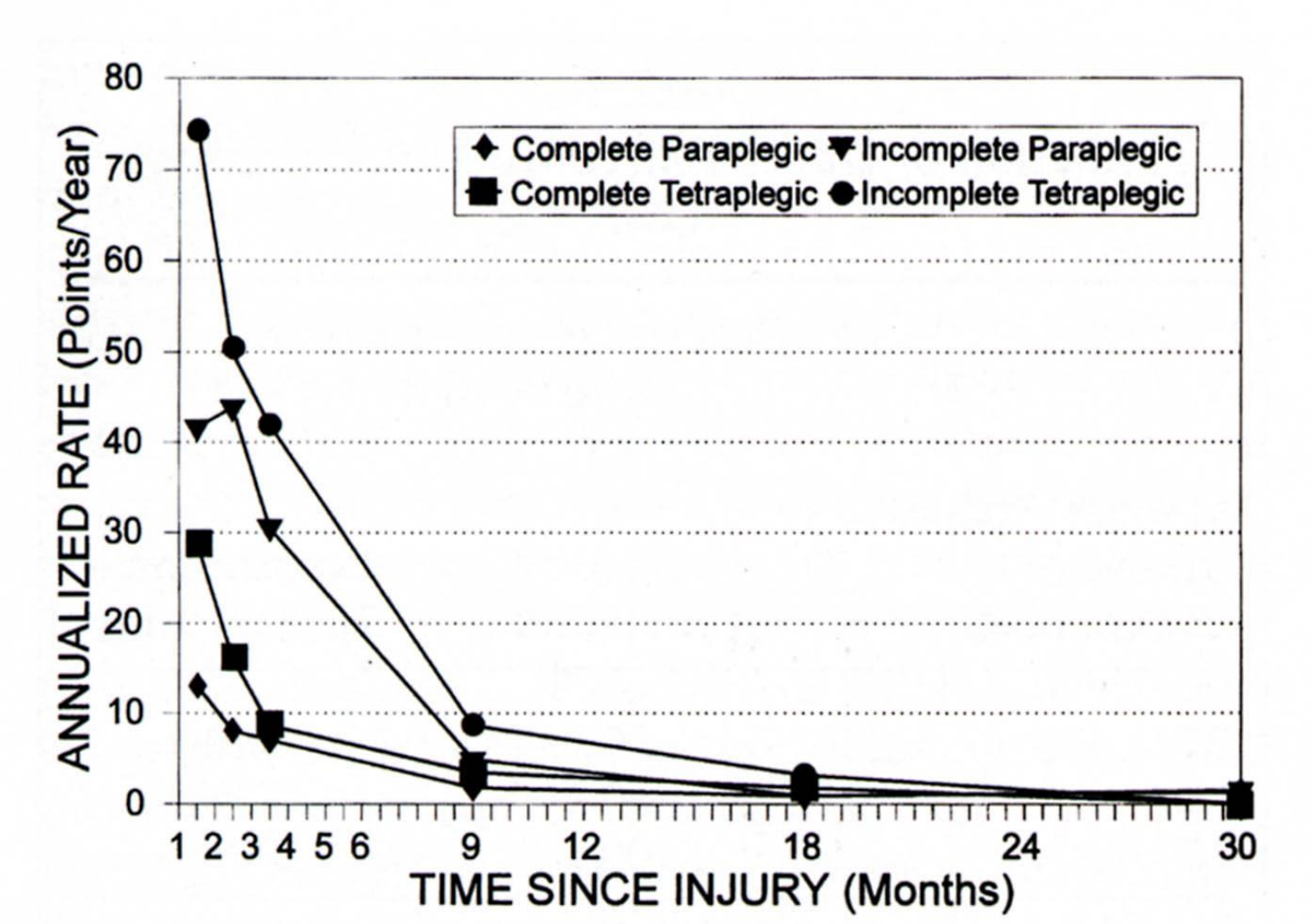
- One year post injury FIM assessments
- 405 survivors with motor complete injuries
- National SCI Statistical Center cases
- Median age of 27

Total Hours of Assistance Required

May exceed 24 hours per day in unusual cases



Motor Score Rate of Recovery Time Course



Prediction of Motor Recovery

Prediction of Lower Extremity Motor Recovery (23)

Manual Muscle Strength at One Month*	Percent with Functional ≥ 3/5 Strength at 1 Year: Complete Paraplegia	Incomplete Paraplegia	Incomplete Tetraplegia
0/5	5%	26%	24%
1/5, 2/5	64%	85%	97%

*ASIA key muscles

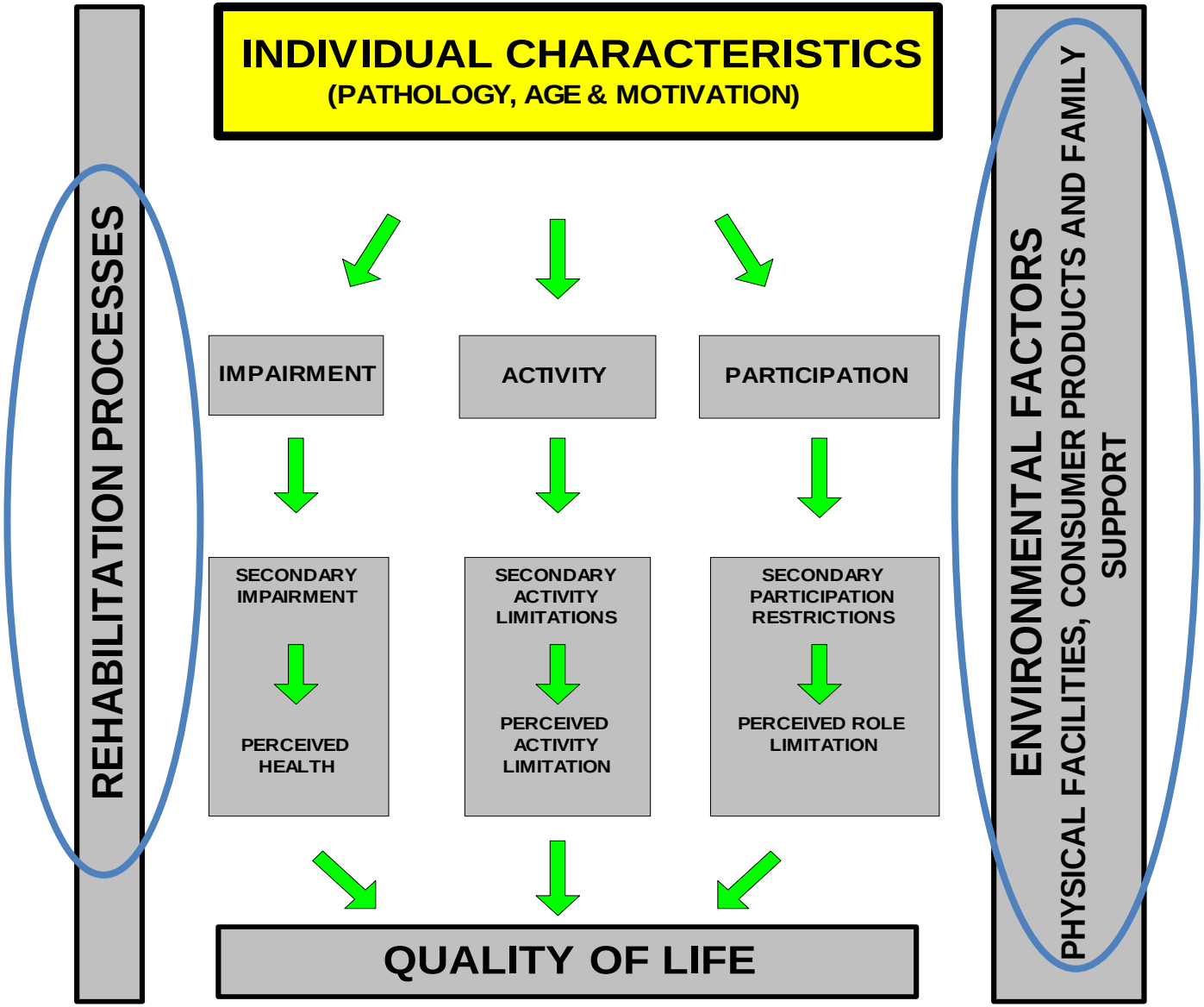
Prediction of Upper Extremity Motor Recovery (23)

Manual Muscle Strength at One Month*	Percent with Functional ≥ 3/5 Strength at 1 Year: Complete Tetraplegia	Incomplete Tetraplegia
0/5	20%	24%
1/5	90%	73%
2/5	100%	100%

*ASIA key muscles

Motor Recovery may translate into decreased burden of care

Centers of Excellence for SCI Cases



Limiting Factors

Examples of what can limit functional outcomes, drive up costs and interfere with re-employment

- Obesity
  - May mean that more than 24 hours of paid care are necessary per day
  - May mandate that extra equipment is necessary
    - e.g., bariatric lift, power wheelchair, oversized shower commode chair, etc.
  - May outgrow custom DME
  - Special bed requirements will drive up costs
  - Off-loading of pressure areas is more difficult
- Pressure sores
- Co-existing brain injury
- Upper extremity impairments apart from SCI effects
- Dependent ICP
- Bowel incontinence

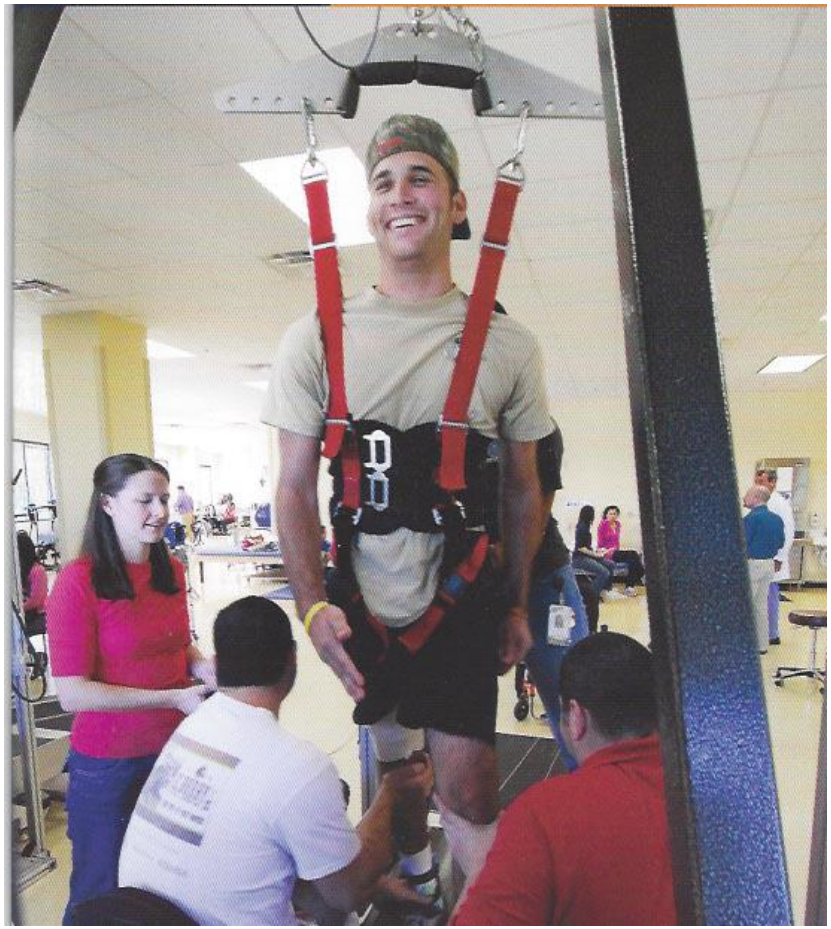
Ambulation Options

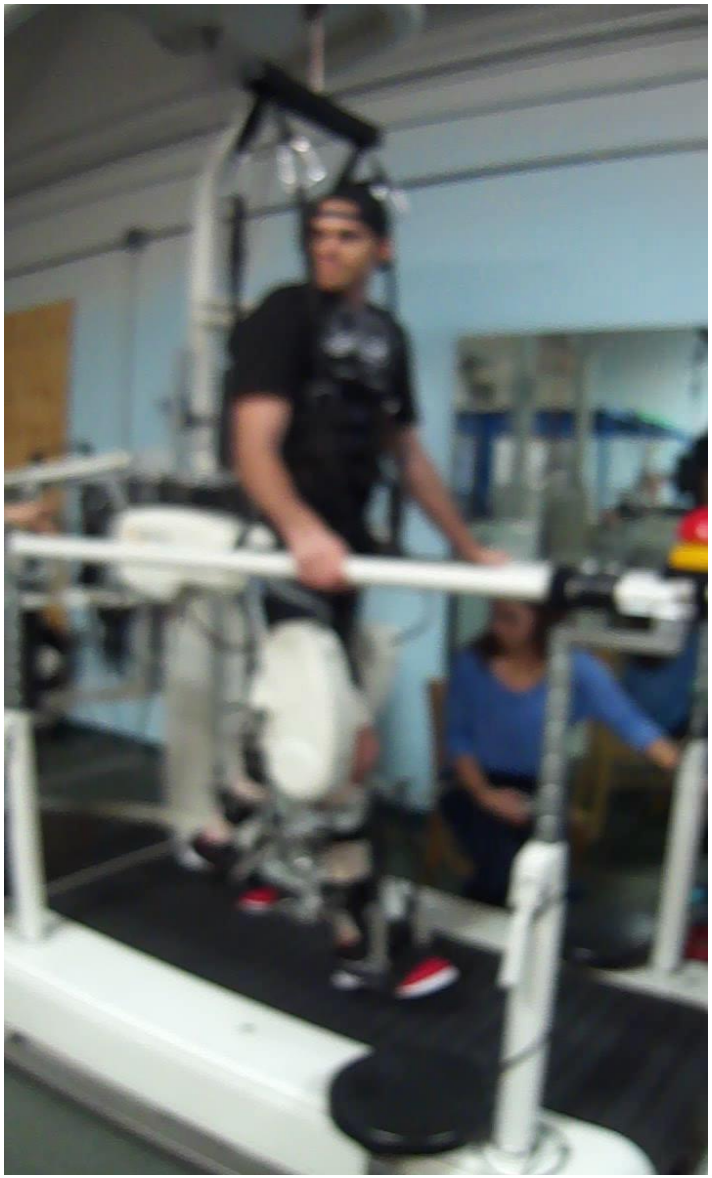
Historical Ambulation Options

- Long leg braces or KAFOs
- Reciprocating gait orthoses
- Short leg braces or AFOs
- Various combinations
- Limitations
  - Body powered, energy inefficient
  - Static balance determines “hands free” ability
  - Fall recovery must be part of the training
- Wheelchair is faster and more efficient

Body Weight Supported Ambulation

"Activity Based Therapy"





Four Exoskeleton Models are Currently in Development

ReWalk

FDA cleared for sale in USA

Indego

Ekso

Rex

Available in UK and New Zealand

Who Qualifies to Use These Devices?

- Persons with SCI or other neurological disorders
- Must have medical clearance for full weight bearing and walking activity
- Must meet certain height and weight limits
- Adults (18 years and older) without unusual risk of fracture (bone density scan to confirm bone health prior to use)
- Must have adequate range of motion at hips, knees and ankles
- Minimal to moderate levels of spasticity may not interfere
- Must tolerate being upright without light headedness
- Skin must be intact where it interfaces with the device

Comparison of Four Systems

System Requires	ReWalk	Indego	Ekso	Rex
Height range	63-75”	61-76”	62-74”	56-76”
Weight range	Up to 220 lbs	Up to 250 lbs	Up to 220 lbs	Up to 220 lbs
Pelvis width			Up to 18”	Up to 15”
Crutch capable	OK	OK	OK	No, joy stick control
Heart health	OK	OK	OK	OK
Bone health	OK	OK	OK	OK
System wt.		26 lbs	50 lbs	
			Also being studied in stroke patients	

Exoskeleton Models

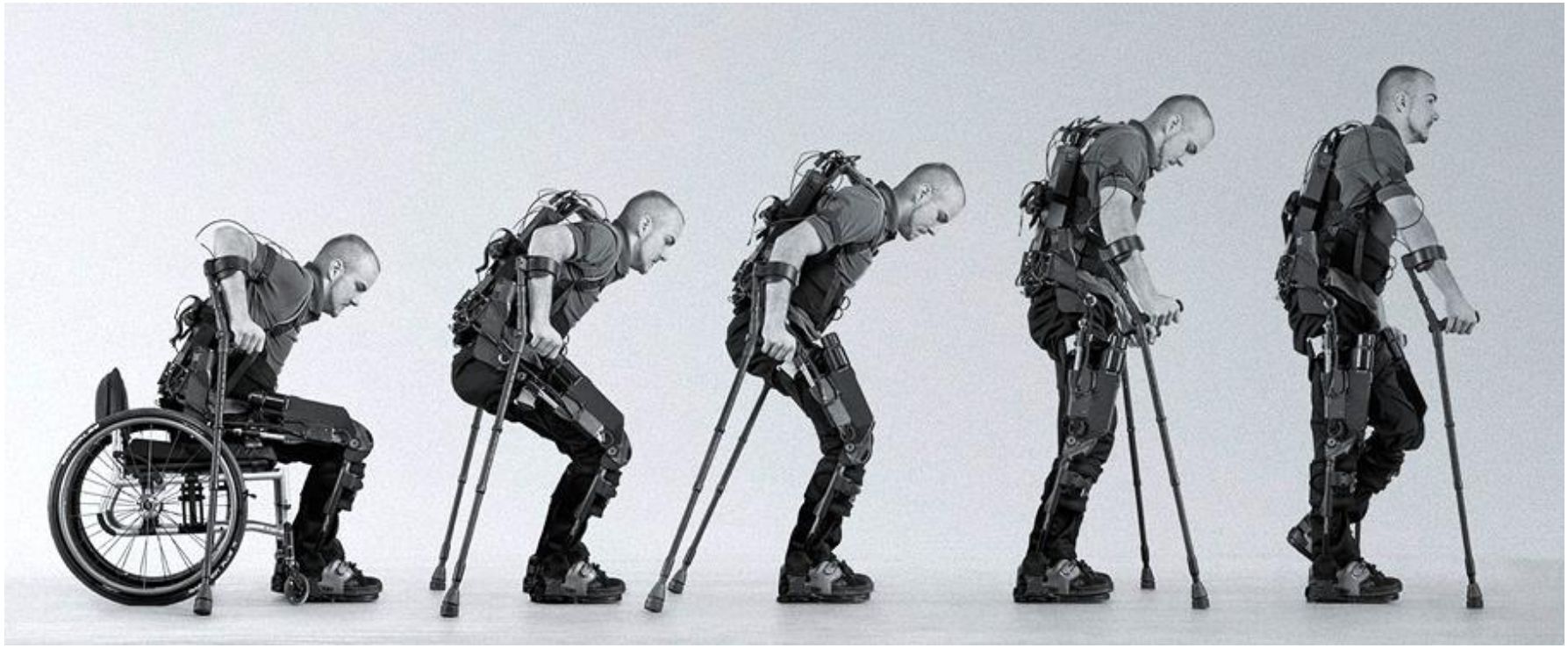
ReWalk

Indego

Ekso

Ekso

"Get Up And Go"



Progressive Training Model for Ekso

FirstStep™

A physical therapist actuates steps with a button push. The user progresses from sit to stand and using a walker to walking with crutches, often in their first session.

ActiveStep™

User takes control of actuating steps via buttons on the crutches or walker.

ProStep™

The user achieves the next step by moving their hips forward and shifting them laterally. The Ekso device recognizes that the user is in the correct position and steps.

NEW ProStep Plus™

Steps are triggered by the user's weight shift PLUS the initiation of forward leg movement.

Ekso User

Rex

- Users should be:
  - Between 56” and 76”
  - Weigh less than 220 lbs
  - Hip width of 15” or less
- Designed for use on solid, stable surfaces, such as those inside the home or workplace.
  - It is not designed for use on slippery, unstable, or soft surfaces, on in areas that contain debris or small objects, such as ice, snow, sand, grass, mud or gravel
- Designed to climb steps that meet typical building code standards for staircases
  - Minimum tread of 12.2”
  - Maximum riser of 7”
- REX can walk on a curbed slope of up to 1:8 (7.1 degrees) and a general slope of up to 1:12 (4.8 degrees).
- REX can walk on a camber of up to 1:50 (1.1 degrees)
- New Zealand and UK

Sophie Morgan - Walking with REX, the hands-free robotic exoskeleton

From Joy Stick Control to Brain Control

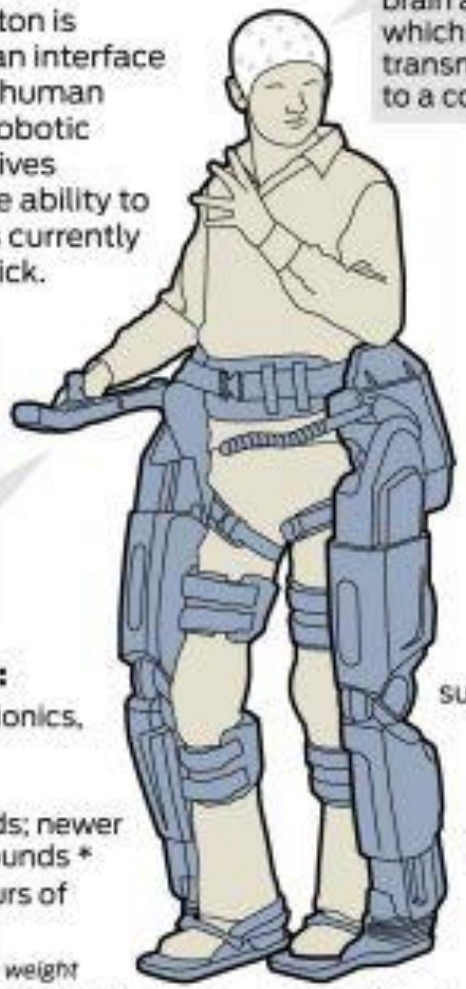
A wearable robot

A research team at the University of Houston is working to create an interface that will allow the human brain to control a robotic exoskeleton that gives paralyzed users the ability to walk. The device is currently controlled by joystick.

How it will work:

1. Sensors on skullcap read brain activity, which is transmitted to a computer

2. The computer translates the brain activity and sends a signal to the exoskeleton, guiding the device without using the joystick



User is supported by leg braces, straps and a harness

About the device:

- **Developer:** Rex Bionics, of New Zealand
- **Cost:** $150,000
- **Weight:** 84 pounds; newer model will be 64 pounds *
- **Battery life:** 2 hours of continuous walking

** User carries none of the weight*

Sources: Rex Bionics; University of Houston

Jay Carr / Houston Chronicle

Potential Benefits, Yet To Be Determined

- Will exoskeleton ambulation replace wheelchair mobility?
- Impact on health, wellness, socialization & psychological benefits?
- Will it potentiate neurological recovery?
- Is it a useful therapeutic modality?
- Will function be improved?
- Will users avoid complications?
- Will long-term health & wellness be facilitated?
- Safety and fall recovery?

Sample Data from an Indego User

Exoskeletons capture data that is useful for setting goals and understanding progress

This is the data collected from "Mr. K," a T7 complete paraplegic, from his eighth time using the Indego.

Data measurement	"Mr. K's" data
Number of steps	1,376
Average speed	0.3 m/s 1 mph = 0.45 m/sec
Exact distance walked	½ mile
Total walking time	45 minutes
User's contribution versus device contribution	Device contributed 100% (Mr. K is a complete para)
Force generated by user's muscles	Mr. K's muscle force provided as much as 95% from quadriceps and 27% from hamstrings with FES alternating 10 steps on/10 steps off

“Sizzle” vs. “Steak”

- *Main Outcome Measures*
  - Walking outcomes include timed walk tests, metabolic cost, gait cycle kinetics, ability to walk on varied surfaces and terrains.
- *Secondary Outcome Measures*
  - Impact on bowel function, bladder function, pain, spasticity, body composition and medication requirements.
- *Quality of Life Measures*
- *Long-term use data*
- *Therefore*:
  - Paradigm is not yet endorsing or recommending purchase of exoskeletons for home use, especially with the supervision requirements and the need for evidence of health benefits and usage data over time.
- The decision about purchase will rest with the payer

Conclusions

- Preliminary studies seem to demonstrate that ***powered exoskeletons*** have potential as mobility devices and to facilitate improvements to body functions and activities for non-ambulatory or poorly ambulatory SCI patients
- ***Not all persons*** are suited to use all or any of these devices
- Technology is in ***early stages*** of development
- Medical ***benefits*** and potential ***risks*** are being defined
- ***Recommendations*** to potential users
    - "Avoid obesity, contractures and osteoporosis to improve your suitability for use of an exoskeleton"
- Health care professionals should critically evaluate the demonstrable benefits and risks of integrating powered exoskeleton ambulation into ***traditional*** rehabilitation programs
- Early incorporation of these systems into clinical research environments may be useful to assist clinicians and researchers in ***rehabilitation programs, in the future, after "cure" interventions***

Thank you!

Q&A